

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products)	MD 15-02641-PHX-DGC
Liability Litigation,)	
)	
)	
<hr/>		
Lisa Hyde and Mark Hyde, a married)	Phoenix, Arizona
couple,)	September 28, 2018
)	
Plaintiffs,)	
)	
v.)	CV 16-00893-PHX-DGC
)	
C.R. Bard, Inc., a New Jersey)	
corporation, and Bard Peripheral)	
Vascular, an Arizona corporation,)	
)	
Defendants.)	
)	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 9 - P.M. SESSION

Official Court Reporter:
Jennifer A. Pancratz, RMR, CRR, FCRR, CRC
Sandra Day O'Connor U.S. Courthouse, Suite 312
401 West Washington Street, Spc 42
Phoenix, Arizona 85003-2151
(602) 322-7198

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared by Computer-Aided Transcription

A P P E A R A N C E S

For the Plaintiffs:

Lopez McHugh

By: **RAMON R. LOPEZ, ESQ.**
100 Bayview Circle, Suite 5600
Newport Beach, CA 92660

Gallagher & Kennedy

By: **MARK S. O'CONNOR, ESQ.**
PAUL L. STOLLER, ESQ.
2575 East Camelback Road, Suite 1100
Phoenix, AZ 85016

Heaviside Reed Zaic

By: **JULIA REED ZAIC, ESQ.**
LAURA E. SMITH, ESQ.
312 Broadway, Suite 203
Laguna Beach, CA 92651

Goldenberg Law PLLC

By: **STUART GOLDENBERG, ESQ.**
MARLENE GOLDENBERG, ESQ.,
800 LaSalle Avenue, Suite 2150
Minneapolis, MN 55402

Lopez McHugh, LLP

By: **JOSHUA MANKOFF, ESQ.**
1 International Plaza, #550
PMB-059
Philadelphia, PA 19113

A P P E A R A N C E S (CONTINUED)

For the Defendants:

Nelson Mullins Riley & Scarborough

By: **JAMES F. ROGERS, ESQ.**

1320 Main Street

Columbia, SC 29201

Snell & Wilmer

By: **JAMES R. CONDO, ESQ.**

400 East Van Buren

Phoenix, AZ 85004

Nelson Mullins Riley & Scarborough

By: **RICHARD B. NORTH, JR., ESQ.**

MATTHEW B. LERNER, ESQ.

ELIZABETH C. HELM, ESQ.

201 17th Street NW, Suite 1700

Atlanta, GA 30363

C.R. Bard, Inc.

Associate General Counsel, Litigation

By: **GREG A. DADIKA, ESQ.**

730 Central Avenue

Murray Hill, New Jersey 07974

I N D E XSUMMARY OF COURT PROCEEDINGSPAGE:

Proceedings Outside the Presence of the Jury 1999, 2081

WITNESSES FOR THE
DEFENDANT:DIRECTCROSSREDIRECT**Christopher Morris, M.D.**

By Mr. Rogers 1970

By Mr. O'Connor 2004

David W. Feigal Jr., M.D.

By Mr. Condo 2023

By Mr. Lopez 2041 2072

Robert Michael Carr Jr.

By Mr. Rogers 2074

INDEX OF EXHIBITSEXHIBITRECEIVED

NO. DESCRIPTION

8538 Radiograph - 2/25/11 1974

8527 CT Image - 2/25/11 compared to 8/26/14 1979

8529 CT Image - 12/16/2011 abdomen and pelvis 1983

8643 Comprehensive and Interventional Pain Management - Medical 1992

8539 4/21/11 Medical Record 1994

4938 Bard Peripheral Vascular Consulting Request Form re Dr. Christopher Morris dated 5/11/2004 2009

6089 Product Development Cycle PPT 2084

INDEX OF EXHIBITS (Continued)EXHIBITRECEIVEDNO. DESCRIPTION

5189	July 10, 2002 IMPRA Recovery Permanent Special 510(k) (K022236)	2094
5187	Aug. 5, 2002 Letter FDA to IMPRA re Recovery (K022236)	2099
5182	Aug. 30, 2002 Letter IMPRA to FDA re Recovery (K022236)	2101
5179	Oct. 4, 2002 Letter FDA to IMPRA re Recovery (K022236)	2104
5178	Oct. 25, 2002 Letter IMPRA to FDA re Recovery (K022236)	2105
5169R	Apr. 25, 2003 Recovery Retrievable Abbreviated 510(k) (K031328)	2107
5197	July 25, 2003 FDA Clearance Letter re Recovery Retrievable (K031328) (Substantial Equivalence)	2108
5301	ETR-05-01-06 Animal Model Evaluation of Recovery Filter G1A Femoral System Report	2111
5304	ETR 05-02-11 G1A Recovery Filter Femoral System Chronic Animal Study Report	2112

P R O C E E D I N G S

(Proceedings resumed at 12:58 p.m.)

(Jury present.)

THE COURT: You may proceed, Mr. Rogers.

MR. ROGERS: Thank you, Your Honor.

CHRISTOPHER MORRIS, M.D.,

called as a witness herein by the defendants, having been previously duly sworn or affirmed, resumed the stand and continued to testify as follows:

DIRECT EXAMINATION (Continued)

BY MR. ROGERS:

Q. Mr. -- not Mr., Dr. Morris, are you ready to proceed?

A. Yes.

Q. Before we took our lunch break, we were looking at the image that's on the screen.

MR. ROGERS: And, Traci, is that still being displayed? It is. Okay.

BY MR. ROGERS:

Q. And had we discussed everything about this particular image that you wanted to show the jury?

A. Yes. I think I was just completing talking about the extent of the thrombus or the clot in that right pulmonary artery.

Q. All right. Let's move to the second page, please.

THE COURT: Folks, that's somebody's cell phone.

1 Everybody, please make sure it's off.

2 JURY MEMBER: Sorry, it's mine.

3 THE COURT: You're the first person who's ever
4 admitted it.

5 All right.

6 MR. ROGERS: Are we ready to proceed, Your Honor?

7 THE COURT: We are.

8 BY MR. ROGERS:

9 Q. All right. So, Dr. Morris, is this another CT image from
10 that --

11 THE COURT: That's somebody else's. Everybody pull
12 out your phone and turn them off.

13 Okay. Go ahead.

14 MR. ROGERS: Thank you, Your Honor.

15 BY MR. ROGERS:

16 Q. Dr. Morris, is what we see here on the screen, 8485, second
17 page, is that another CT image from that same series?

18 A. Yes.

19 Q. And can you tell the jury what we see here.

20 A. So this is a -- a section a little more what we say is
21 posterior, closer towards the back. And we're seeing a little
22 bit more of the left pulmonary artery. And this dark area is a
23 smaller clot in the descending left pulmonary artery.

24 We're also seeing part of the spine because we're
25 further back, and there's some degenerative, what we say,

1 spondylosis, degenerative arthritis of the dorsal spine as
2 well.

3 Q. Now, Dr. Morris, is it correct to say that at this time
4 Mrs. Hyde had what is known as bilateral pulmonary embolism?

5 A. Yes.

6 Q. And what does that mean?

7 A. That means --

8 THE COURT: Well, maybe it's not a phone. We'll try
9 to adjust the mics.

10 THE WITNESS: So that means --

11 May I start or --

12 THE COURT: Yeah, go ahead.

13 THE WITNESS: Okay. That means that the clot that
14 came up to the main pulmonary artery either broke up and went
15 to both sides, the right and the left lung, or there were
16 multiple clots that came up and went to the right as well as
17 the left lung.

18 BY MR. ROGERS:

19 Q. And how did Mrs. Hyde's doctors try to treat or deal with
20 this pulmonary embolism?

21 THE COURTROOM DEPUTY: Not quite sure --

22 THE COURT: Let's do our best. We'll call Brian up to
23 check it out.

24 MR. ROGERS: Can everyone hear okay?

25 If it's just a matter of having some static, Your

1 Honor, I'm glad to proceed.

2 THE COURT: Please.

3 BY MR. ROGERS:

4 Q. Okay. So, Dr. Morris, what did Mrs. Hyde's doctors do to
5 try and treat this issue?

6 A. They decided to treat her with anticoagulation, first
7 heparin and then converting eventually over to an oral pill
8 form of warfarin.

9 Q. And warfarin is the same thing as Coumadin?

10 A. Yes.

11 Q. And so did the doctors who were caring for Mrs. Hyde at the
12 time, did they ultimately decide that an IVC filter should also
13 be placed?

14 A. Yes, they did.

15 Q. And have you reviewed the images that are available from
16 the placement of the IVC filter?

17 A. Yes, I have.

18 MR. ROGERS: And, Scott, would you mind pulling up
19 Exhibit 8538, please.

20 And can you bring out the center section a little bit?
21 Is that possible with this image?

22 BY MR. ROGERS:

23 Q. Okay. Can you see that, Dr. Morris?

24 A. Yes, I can.

25 Q. And just to orient the jury, can you tell the jury what

1 procedure is going on here? What are we seeing?

2 THE COURT: This is not in front of the jury,
3 Mr. Rogers.

4 MR. ROGERS: Oh, I'm sorry. Thank you, Your Honor. I
5 apologize.

6 THE COURT: I don't think it's in evidence either.

7 MR. ROGERS: Your Honor, I would move this into
8 evidence.

9 THE COURT: Any objection?

10 MR. O'CONNOR: Can I get the exhibit number again,
11 please?

12 MR. ROGERS: Sure. It's 8538.

13 MR. O'CONNOR: No objection.

14 Are you going to ask him about --

15 Can we get the date of this particular radiograph from
16 the witness, Your Honor?

17 THE COURT: Yes. Let's go ahead and do that.

18 The exhibit is admitted, and you may display it.

19 (Exhibit No. 8538 admitted into evidence.)

20 MR. ROGERS: Thank you, Your Honor.

21 MR. O'CONNOR: Thank you.

22 BY MR. ROGERS:

23 Q. So, Dr. Morris, first of all, what's the date of this film?

24 A. February 25th, 2011.

25 Q. Thank you.

1 Now, can you orient us and tell us what it is we're
2 seeing, what kind of procedure is going on?

3 A. Yeah. So this is the lumbar spine. It's curved a little
4 bit to the left. That's called scoliosis. But there's the
5 delivery device here that was used to place the filter. So
6 this is going to be eventually taken out.

7 And it's hard to see because this is somewhat of a
8 blurry picture that Dr. Henry took during the procedure, it's
9 called a radiographic spot film, but this shows the IVC filter
10 in place. And the nose of that filter is terminating at the
11 lower margin, at least at the level of the lower margin of the,
12 what we call the pedicle.

13 This is the left pedicle. And the right pedicle would
14 be seen here. Because she has the scoliosis and the curvature,
15 we're not seeing it as well, but it's at that lower margin of
16 the right pedicle of the L-2 vertebral body. This is L-2.
17 This is -- meaning lumbar vertebral body number 2. So that's
18 our reference point.

19 Q. And when you use the term the "nose" of the filter --

20 A. Yes.

21 Q. -- what do you mean by that?

22 A. I mean the top part. Just above it is a hook that we can
23 barely see because the image is somewhat poor quality, but it's
24 the most cranial directed portion of the filter.

25 Q. And based on this image that you see, and other images that

1 you've seen of this filter, can you say what specific filter
2 this is, as far as the type?

3 A. No. All we know is that there is a hook, so it's somewhat
4 a later version than the G2, because the G2 did not have a
5 hook. But we can't tell if this is a G2 Express, a G2X, an
6 Eclipse. We know it's probably not --

7 MR. O'CONNOR: Objection, Your Honor. This is not in
8 the report about a question of what filter --

9 THE COURT: All you have to say is "nondisclosure."

10 MR. O'CONNOR: Nondisclosure.

11 THE COURT: Is it in the report?

12 MR. ROGERS: He says what type it is in the report,
13 Your Honor, but this particular stuff is not in the report.

14 THE COURT: Objection is sustained.

15 MR. ROGERS: Thank you, Your Honor.

16 BY MR. ROGERS:

17 Q. And so can you tell us about the position of this filter?
18 Would you consider this a well-placed filter?

19 A. Yes. It's well positioned.

20 Q. And how about as far as it being centered and upright?
21 Would you consider it to be those things?

22 A. Yes.

23 MR. ROGERS: We can take that down, Scott.

24 BY MR. ROGERS:

25 Q. Let me ask you about some of the -- some of the issues in

1 this case that the jury's heard about related to Mrs. Hyde's
2 filter.

3 And why don't we start with tilt. Did you review
4 various images of this filter throughout the course of time?

5 A. Yes, I did.

6 Q. And does that take you from the implant of the filter all
7 the way up to the time that it was explanted?

8 A. Yes.

9 Q. And what is your opinion, to a reasonable degree of medical
10 certainty, of whether or not this filter was tilted?

11 A. I saw no significant amount of tilt in this filter.

12 Q. And did you -- the jury's heard that this filter is tilted
13 2 to 4 percent. Would you think that that's accurate?

14 A. I can't say it's not tilted 2 to 4 percent, but that's such
15 a small degree of tilt that we don't really have a good way to
16 measure that tiny amount of tilt.

17 Q. All right. Well, let's move on and talk about caudal
18 migration. And can you tell the jury what that is, please.

19 A. Caudal migration is movement of the entire filter towards
20 the feet.

21 Q. And when your -- people such as yourself, interventional
22 radiologists, are there standards within your organization
23 about migration of a filter?

24 A. Yes.

25 Q. And can you describe for the jury what those standards say?

1 A. The Society of Interventional Radiology defines migration
2 to be at least 2 centimeters, or 20 millimeters, in distance.

3 Q. And why is that? Why is that sort of the threshold?

4 A. Because smaller degrees of apparent migration may or may
5 not be true migration. It may be accounted for by other
6 factors such as the way the image was created.

7 There's a phenomenon called parallax. Because when an
8 x-ray is made, they're not all orthogonal beams. They may
9 diverge. And if the object that we're looking at is on the
10 edge of the film or not exactly in the middle, it may be
11 projected or shadowed further away than where it really is.

12 There are other factors, such as hydration of the
13 patient. In patients that are really well hydrated, the IVC
14 will dilate up in diameter, and that can then widen the struts
15 and then lower the nose of the filter based on the physics of
16 the way the filter is presented.

17 And other factors like respiratory variation can
18 change that apparent location of the filter. Cardiac issues.
19 Patients that have reflux or congestive heart failure will have
20 a more dilated IVC at various times as well. So lots of
21 factors that can change subtle amounts of apparent migration
22 when it's really not even migration.

23 MR. ROGERS: Can we have Exhibit 8527, please.

24 And, Your Honor, I move this into evidence.

25 MR. O'CONNOR: No objection.

1 THE COURT: Admitted.

2 (Exhibit No. 8527 admitted into evidence.)

3 MR. ROGERS: May we display?

4 THE COURT: Yes.

5 BY MR. ROGERS:

6 Q. All right. So, Dr. Morris, can you see that image on your
7 screen?

8 A. Yes. I can see both of them.

9 Q. And on the left-hand side, is that the image that we just
10 saw of the IVC filter at the time of implant?

11 A. Yes.

12 Q. And what do we see on the right-hand side?

13 A. This is a much more clear spot film that Dr. Kuo obtained
14 when he -- right before he was going to remove this filter.

15 Q. So on the left-hand side we have the filter when it was
16 placed, and on the right-hand side we have the filter right
17 before it was retrieved; is that right?

18 A. Yes.

19 Q. And so what can you tell the jury, Dr. Morris, about what
20 you observe here about whether this filter caudally migrated?

21 A. Well, we know that this is the pedicle, and I'll outline
22 the actual ped -- right pedicle of L-2.

23 So when this filter was placed, this nose was in --
24 projected over -- right where the tip of my arrow is right now.
25 And based on where it is now, it has, you know, changed its

1 apparent position a very small amount.

2 Q. And would the amount of change that you could perceive in
3 these images, would that be more or less than 5 millimeters?

4 A. Less than 5 millimeters.

5 Q. And so according to the standards applied by the Society of
6 Interventional Radiologists, would that be considered to be
7 migration?

8 A. Absolutely not.

9 Q. And is that because it's within the margin of error that
10 you just described?

11 A. Yes.

12 Q. All right. Dr. Morris, I want to move on to perforation.

13 MR. ROGERS: And you can take that image down, Scott.

14 BY MR. ROGERS:

15 Q. Because the jury's also heard about perforation. Can you
16 describe for the jury what perforation is.

17 A. Perforation is when a strut of an IVC filter extends
18 through the wall of the inferior vena cava.

19 Q. And are there an accepted grading system that is available
20 to interventional radiologists such as yourself in order to
21 assign the level of perforation that can be observed?

22 MR. O'CONNOR: Objection. Nondisclosure.

23 MR. ROGERS: Your Honor, in the Hyde report, it's on
24 page 8, starting at line 5.

25 THE COURT: Page 8 -- oh. That's not in his main

1 report?

2 MR. ROGERS: No, sir, Your Honor. It's in --

3 THE COURT: Okay.

4 MR. ROGERS: You got it?

5 THE COURT: I see it.

6 Objection is overruled.

7 BY MR. ROGERS:

8 Q. All right, Dr. Morris. So is there a grading system that
9 is available to interventional radiologists such as yourself in
10 order to place an amount of how much an IVC filter may have
11 perforated?

12 A. There are multiple grading systems. The one that I like to
13 use was basically described by Oh and Trerotola a number of
14 years ago.

15 Q. And when you say Oh, is that a person's name?

16 A. Yes.

17 Q. And that's spelled how?

18 A. O-H.

19 Q. And do you know Dr. Oh?

20 A. I don't know him, no.

21 Q. And do you know what institution he practices at?

22 A. I think they're all at University of Pennsylvania.

23 Q. And so let's talk about this grading system. And so as I
24 understand it --

25 Well, let me ask you: What is the lowest level of

1 perforation under this grading system?

2 A. Grade 0.

3 Q. And what does that mean?

4 A. That basically means there is zero -- there is no
5 penetration at all. The strut is entirely within the lumen or
6 the inside of the inferior vena cava.

7 Q. And what's the next grade after grade zero?

8 A. 1. Grade 1.

9 Q. And what does that mean?

10 A. That means that the strut may or may not actually be
11 piercing through the wall. It may still be within a thickened
12 part of the wall of the IVC on an x-ray or an inferior vena
13 cavagram type of a study. It may appear like it's outside, but
14 it's what we call tenting. It may just be pushing the wall out
15 a little bit in a thickened area, so it's not true
16 through-and-through penetration.

17 Q. And so what is the next level after Grade 1?

18 A. Grade 2.

19 Q. And can you explain to the jury what that is?

20 A. That means the strut is terminating clearly outside of the
21 inferior vena cava and it is within the fat, called the
22 retroperitoneal fat, around the inferior vena cava.

23 And typically on a CT scan -- because that's how these
24 are diagnosed, by CT scanning -- there is a metal artifact, so
25 there is like what we call a halo around the metallic part of

1 the strut that's within the fat of the retroperitoneum.

2 Q. And is the next level Grade 3?

3 A. Correct.

4 Q. I catch on to these things.

5 And so what -- can you describe what Grade 3 is?

6 A. Grade 3 means that the strut is interacting with a
7 structure outside of the inferior vena cava.

8 Q. And, Doctor, before we move on, are things like an inferior
9 vena cava, are they what we call radiopaque? I mean, can they
10 be seen on an x-ray?

11 A. Not inherently on a standard radiograph or x-ray study, no.

12 Q. Okay.

13 MR. ROGERS: Scott, let's pull up Exhibit 8529,
14 please.

15 And, Your Honor, I move this into evidence.

16 MR. O'CONNOR: No objection.

17 THE COURT: Admitted.

18 (Exhibit No. 8529 admitted into evidence.)

19 BY MR. ROGERS:

20 Q. And, again, Dr. Morris, to get us oriented, what's the date
21 of this study?

22 A. This is December 16th, 2011.

23 Q. And what was going on at this point in time clinically with
24 Mrs. Hyde that caused this study to be ordered?

25 A. Several days before this, maybe four or five days before,

1 she had -- Mrs. Hyde had an ultrasound study of her kidneys
2 because they suspected kidney stones. And that study actually
3 did show bilateral kidney stones, and so that prompted this
4 study to be performed.

5 Q. And, Doctor, do you have with you a mouse there that you --

6 A. I do.

7 Q. -- can manipulate this image?

8 A. I do.

9 Q. And before we do that, can you tell the jury, when you're
10 in your office or in your hospital looking at CT images, what
11 do you do in order to kind of move through the series of
12 images?

13 A. Well, we can do what we call scroll through the set of
14 images from either top to bottom or bottom to top.

15 Q. And can you just demonstrate for the jury what that means,
16 what you're going to do?

17 A. Okay. So I'm just slowly scrolling through these images
18 now from the top, and now I'm coming down --

19 MR. ROGERS: Oh, I'm sorry, Your Honor. May we
20 display?

21 THE COURT: You may.

22 MR. ROGERS: I apologize.

23 BY MR. ROGERS:

24 Q. So I apologize. But can you start again?

25 A. Okay.

1 Q. I guess from the bottom.

2 A. So this is -- well, I'm actually starting from the top.
3 This is the highest part. And we can see the liver over in
4 this location.

5 This is the inferior vena cava. No contrast media or
6 dye has been administered in this study because it's been
7 performed to look more for kidney stones. So that's why they
8 did not give the dye or the contrast media.

9 So as I scroll slowly from top to bottom, we'll start
10 to see the nose of the filter dead center within the middle of
11 the inferior vena cava. If I draw a circle around the inferior
12 vena cava, that bright spot right in the middle is the nose.
13 So I'm going to keep coming down in an inferior direction, and
14 we start to see the strut start to become in view.

15 And, by the way, here is the right kidney stone just
16 seen incidentally there.

17 As I come down another section, we now see these outer
18 struts. There's six outer struts, which are the arms of this
19 filter. And there are -- if you count closely, there are six
20 inner struts. Those are the legs of the filter. Everything
21 seems to be really well positioned. No detectable tilt
22 identified here.

23 As we keep coming down, there's a well distribution of
24 the outer arms and the -- the six outer arms and the six inner
25 legs.

1 I'll come down one more section, and we're seeing --
2 imagine a clot coming up, and it's going to get stuck right in
3 the middle. If I go up a little bit, that's what the clot
4 sees. That's how these filters work.

5 I'm going to come back down again.

6 And I touched that screen. That red dot should not be
7 there, so I'll go undo. Okay.

8 Keep coming down. And now we start to see what may be
9 considered -- what may end up appearing to be perforation. We
10 can see that this strut, for instance, where my cursor is, is
11 getting towards the confines of that inferior vena cava wall.
12 But also notice that the inferior vena cava is draped over the
13 spine. I mean, there's no -- there's no retroperitoneal fat.
14 This is what fat looks like. It's dark.

15 There's no intervening fat, so that inferior vena cava
16 is literally on top of the vertebral body, which is this
17 structure here. There's also bowel right up on top of it, so
18 there's not much room there for things to -- you know, to let
19 fat get insinuated in between these structures.

20 As we keep coming down, we're starting to lose the
21 arms because they're shorter than the legs. But here is an arm
22 that is interacting with the aorta. This structure here is the
23 aorta. So we don't know if it's actually touching it or
24 touching the outer wall or right adjacent to it. That's why we
25 just use this sort of vague term "interacting" because we don't

1 know exactly what it's doing.

2 And these other struts, some of those are Grade 1 or
3 Grade 2 because we don't know whether they're actually tenting
4 or within the retroperitoneal fat. I don't see any halo around
5 them, so I can't clearly call them Grade 2.

6 But that's what the kind of things we're looking at
7 when we're evaluating these filters at that point.

8 Q. And based on your review of this image, do you see any
9 indication that a strut of the filter has pierced into the
10 aorta?

11 A. Into the aorta, no.

12 Q. And do you see any indication in this study where you could
13 say, to a reasonable degree of medical certainty, that one of
14 the filter struts has entered the patient's spine?

15 A. I can't say that, because if we look up high, you can see a
16 distance here between the wall of the inferior vena cava and
17 the vertebral body, which is part of the spine.

18 But as we come down where we may think some of these
19 struts could theoretically be penetrating, everything's against
20 the spine. So we can't tell if they're still within the IVC or
21 they're right next to the outside of the IVC, so there's -- we
22 can't, with a degree of certainty, tell whether or not they're
23 actually penetrating into the spine at that location.

24 Q. And, Doctor, did you review other CT images that are
25 similar to this in that same axial plane from 2013 and 2014?

1 A. Yes, I did.

2 Q. And what can you tell the jury about these struts and their
3 position and whether they changed over time?

4 A. Everything looked pretty much exactly the same except for
5 the last CT scan of May of 2014 showed a missing arm, which we
6 know had fractured at this point and had embolized to the right
7 ventricle of the heart.

8 Q. And, Doctor, if you were reviewing this imaging in regard
9 to perforation, would this be of any clinical concern to you?

10 A. Which part?

11 Q. As far as the strut positions as far as perforation is
12 concerned.

13 A. Oh, we see this routinely. All types of filters.

14 Q. And would this be of any clinical concern?

15 A. No.

16 Q. So, Doctor, let's talk about fractures, since you brought
17 that up. And you mentioned an image from May of '14; is that
18 right?

19 A. Yes.

20 MR. ROGERS: And so, Scott, if you would, can you pull
21 up Exhibit --

22 Well, I take it back. I don't have it.

23 BY MR. ROGERS:

24 Q. Let's just talk about it, Doctor.

25 And you reviewed that image; correct?

1 A. Yes.

2 Q. And so when you saw the image, was one of the struts, had
3 it disappeared?

4 A. Yes.

5 Q. And so can you pinpoint a time at which we knew that the
6 strut was still in place and when we knew it was gone?

7 A. Yes. We know that that strut was in place on the CT scan
8 of the abdomen and pelvis June of 2013, and it was not there on
9 the next CT scan that was obtained in May of 2014. So sometime
10 in that window, that strut had fractured and embolized.

11 Q. And did you review any CT images of the strut itself in the
12 patient's heart?

13 A. Yes.

14 Q. And what did those show?

15 A. Those showed the strut that looked like an arm was in the
16 right ventricle of the heart.

17 Q. All right. So, Doctor, let's talk about the removal of the
18 filter and the strut.

19 And can you remind the jury where that procedure took
20 place?

21 A. That was done at Stanford University Hospitals by Dr. Kuo.

22 Q. And have you reviewed the imaging that was taken during
23 that procedure that relates to the removal of the filter?

24 A. Yes, I have.

25 Q. And can you describe for the jury the process that Dr. Kuo

1 used to remove that filter?

2 A. He used -- well, first of all, he entered the venous system
3 by puncturing the right internal jugular vein in the neck, and
4 he advanced a catheter down the venous system and into the
5 inferior vena cava where he took pictures of what -- with
6 what's called an inferior vena cavagram. He wanted to make
7 sure there was no clot trapped in the filter which would
8 preclude removing it.

9 And after that, he was then able to exchange that
10 catheter for the sheath system. A sheath is basically just a
11 bigger catheter. These are all routine techniques that we use
12 to remove filters. And that sheath was placed down right near
13 the top of the filter. And through that sheath he inserted
14 what's called a snare, a catheter and snare, a gooseneck snare,
15 or in this case he used a tri -- a tri-loop snare, which is a
16 special guidewire that forms a loop.

17 And then he can use that loop, and he did use the
18 loop, to engage the hook of that filter. He pushed his
19 catheter down over the loop to basically cinch down that snare
20 wire on that hook. Then he could actually pull the whole
21 filter system directly into the sheath and out of the body.
22 And that's exactly what he did.

23 Q. And, Doctor, were there any instruments used that were
24 special instruments to remove that filter?

25 A. He only used a catheter and loop snare. That's the most

1 simple technique known to remove a filter. And he did not use
2 any advanced techniques to remove that filter.

3 Q. And so, Doctor, did you also review the imaging of the
4 removal of the strut from the heart?

5 A. There was -- there was not much in the way of imaging,
6 because they did that primarily by real-time fluoroscopy and
7 didn't really save images. But he did describe the whole
8 process in his report, so I did review his report very well,
9 yes.

10 Q. And, Doctor, did the -- was Dr. Kuo successful in the
11 removal of the strut?

12 A. Yes.

13 Q. And so once the procedure was over, were all the portions
14 of the IVC filter out of the patient at that time?

15 A. Yes.

16 Q. Doctor, let me again sort of move forward. I want to kind
17 of change topics, and I want to talk to you about some things
18 that the jury's heard through the trial.

19 And the first thing I want to talk to you about are
20 potential symptoms that were caused by the filter. And do you
21 have an opinion, to a reasonable degree of medical certainty,
22 as to whether the filter or the strut caused Mrs. Hyde to
23 experience any abdominal pain or back pain?

24 A. Yes, I do.

25 Q. And what is that opinion?

1 A. Well, she has -- Mrs. Hyde has so many problems that can
2 cause abdominal pain and back pain. We know that a lot of
3 those problems commonly cause abdominal pain and back pain.
4 IVC filters rarely cause pain, so I think the likelihood of the
5 filter causing those symptoms is less than the likelihood of
6 her other concomitant disease processes causing those same
7 symptoms.

8 Q. And did you see records that indicated that there had been
9 issues about back pain that were long-standing?

10 A. Yes.

11 MR. ROGERS: And, Scott, would you mind pulling up
12 Exhibit 8643, please.

13 Your Honor, I move this into evidence.

14 MR. O'CONNOR: I'm just having a hard time seeing the
15 date. I'm sorry.

16 MR. ROGERS: Sure. Up at the top.

17 MR. O'CONNOR: All right. Thank you.

18 No objection.

19 MR. ROGERS: Your Honor, may we display?

20 THE COURT: Admitted.

21 Yes, you may display.

22 (Exhibit No. 8643 admitted into evidence.)

23 MR. ROGERS: Thank you.

24 So just to get oriented, Scott, would you pull up the
25 top thing there.

1 BY MR. ROGERS:

2 Q. And so, Doctor, to help us know what we're seeing, can you
3 tell us the date of this record and what's going on here.

4 A. This visit date was May 13th, 2013. It was a visit by
5 Dr. -- I don't know how to pronounce it, but "Reyes," "Reyes."
6 And it was in the Comprehensive Interventional Pain Management
7 portion of this healthcare system.

8 MR. ROGERS: And, Scott, you can take that down, that
9 box.

10 And can you pull out the -- not the next box down but
11 the next box, please.

12 BY MR. ROGERS:

13 Q. And so, Doctor, in this particular portion, was there
14 anything that you thought that was significant regarding the
15 length of time that the patient had had issues with back pain?

16 A. Well, it describes it as a chronic problem and -- have to
17 read through here, but it looks like Mrs. Hyde described --
18 described it as it was precipitated by a fall into a trench.

19 Q. And when is the date that was relayed about when that fall
20 occurred?

21 A. September 24, '07. 2007.

22 Q. All right. Thank you.

23 MR. ROGERS: And, Scott, you can take that down.

24 BY MR. ROGERS:

25 Q. And let me ask you about another topic that the jury has

1 heard some evidence of, and that is evidence of sleep
2 difficulties.

3 In your review of the records, did you see records
4 that you thought were important regarding how long those issues
5 had been going on?

6 A. Yes, I did.

7 MR. ROGERS: And, Scott, can we pull up Exhibit 8539,
8 please.

9 And, Your Honor, I move this into evidence.

10 MR. O'CONNOR: No objection.

11 THE COURT: Admitted.

12 (Exhibit No. 8539 admitted into evidence.)

13 MR. ROGERS: May we display?

14 THE COURT: Yes.

15 BY MR. ROGERS:

16 Q. And, Dr. Morris, if you would, can you again just orient
17 the jury to what we're seeing here, when this is and what it
18 is?

19 A. Sure. The date here is April 21st, 2011. That's several
20 months after the IVC filter was placed.

21 Q. And just as a reminder, the filter was placed in February
22 of 2011; is that correct?

23 A. Yes.

24 Q. So at this point in time, approximately how long had the
25 filter been indwelling?

1 A. About two months.

2 Q. And so, Doctor, if we could --

3 MR. ROGERS: Scott, can you pull up the second
4 paragraph, please.

5 BY MR. ROGERS:

6 Q. And, Doctor, was this an evaluation by a sleep specialist?

7 A. Yes, a sleep neurologist.

8 Q. And what did you see in this record that you thought was
9 important about the length of time that these issues had been
10 going on?

11 A. Well, she described sleep issues for quite a long time.
12 And, you know, she goes on to talk a lot more about, at least
13 to Dr. Treisman here, about the actual symptoms that she
14 experiences at night and why she can't sleep well. But she'd
15 been treated with a CPAP, you know, a continuous positive
16 airway pressure machine, for quite a while before this.

17 Q. And, Doctor, does this record indicate that the patient had
18 at night felt like she was going to die and she is gasping for
19 air?

20 A. Yes, it does.

21 Q. All right. Thank you.

22 And, Doctor, let me ask you, I guess, just a couple of
23 more questions. You know, the jury has also heard about chest
24 pain and whether it may be related to the strut that was in the
25 heart.

1 And let me ask you: Do you have an opinion, to a
2 reasonable degree of medical certainty, as to whether the
3 patient experienced chest pain from the strut?

4 A. Yes.

5 Q. And what is that opinion?

6 A. Well, number one, I know based on studies that I've read
7 and analyzed that fractured fragments rarely cause symptoms.
8 Fractured fragments in the heart or in the pulmonary arteries
9 rarely cause symptoms.

10 MR. O'CONNOR: Objection. Lack of disclosure on this,
11 Your Honor.

12 MR. ROGERS: Your Honor, we'll move on.

13 THE COURT: All right.

14 BY MR. ROGERS:

15 Q. So to kind of narrow your opinion down a little bit,
16 Doctor, as far as Mrs. Hyde specifically is concerned, what is
17 it that made you reach this conclusion?

18 A. Well, she has lots of underlying medical issues that are
19 commonly associated with chest pain, GE reflux disease being
20 one of them. She had cervical spinal -- does have cervical
21 spinal stenosis and a bulging disk in her cervical spine. And
22 we know from her imaging that she has diffuse spondylosis of
23 her thoracolumbar spine with bridging osteophytes and rotatory
24 sigmoid scoliosis. All those can cause pain in the chest area.

25 MR. O'CONNOR: Your Honor, I move to strike this

1 testimony as nondisclosed.

2 THE COURT: Mr. Rogers?

3 MR. ROGERS: Your Honor, that's fine. We'll move on.

4 THE COURT: Well, I will grant the motion and instruct
5 the jury to disregard the last answer.

6 BY MR. ROGERS:

7 Q. And let me ask you this, Dr. Morris: In your experience as
8 an interventional radiologist, do you perform procedures from
9 time to time on patients' hearts?

10 A. Well, we do retrieve foreign bodies in the heart, yes. We
11 also pass catheters through the heart to gain access to the
12 pulmonary artery system.

13 Interventional radiologists, many, many years ago, did
14 a lot of the early interventional procedures directly on the
15 heart, but I personally only -- I restrict myself to the types
16 of procedures I just mentioned.

17 Q. And are you familiar with procedures where there are pieces
18 of metal that are intentionally placed in a patient's heart for
19 their health?

20 A. Yes.

21 Q. And what would that be?

22 A. Pacemaker. Pacemaker leads are placed in the heart all the
23 time. Very commonly.

24 MR. O'CONNOR: Objection. Nondisclosure.

25 THE COURT: Where is that, Mr. Rogers?

1 MR. ROGERS: Your Honor, I believe it's in there, but
2 I'm not going to take the time to find it.

3 THE COURT: All right. Objection is sustained.

4 BY MR. ROGERS:

5 Q. All right. So, Dr. Morris, let me ask you this: Are you
6 aware of any literature on struts in hearts causing patients
7 death or to be at risk of sudden death?

8 A. I've never seen a report of that, no.

9 MR. O'CONNOR: Objection. Nondisclosure.

10 THE COURT: Where is that, Mr. Rogers?

11 MR. ROGERS: Your Honor, I believe it's page 9,
12 number 5.

13 THE COURT: Of the Hyde report?

14 MR. ROGERS: No. I take it back, Your Honor. Top of
15 page 10, number 6. Next to the last sentence.

16 THE COURT: Objection is overruled.

17 BY MR. ROGERS:

18 Q. And, Dr. Morris, just to conclude, if you were Mrs. Hyde's
19 doctor, what would you tell her today about what impact that
20 this -- the filter and the strut would have on her?

21 A. So I would probably be seeing -- see her in my office, and
22 I would sit down with her and counsel her --

23 MR. O'CONNOR: This is -- nondisclosure.

24 THE COURT: Where is this disclosed, Mr. Rogers?

25 MR. ROGERS: Your Honor, that specific thing is not in

1 the report.

2 THE COURT: Objection is sustained.

3 Let's stick to the report and the deposition.

4 MR. ROGERS: Thank you, Your Honor.

5 BY MR. ROGERS:

6 Q. Dr. Morris, have all the opinions that you've expressed
7 today been to a reasonable degree of medical certainty?

8 A. Yes, they have.

9 MR. ROGERS: All right. Thank you. I have no further
10 questions at this time.

11 THE COURT: Cross-examination.

12 MR. O'CONNOR: May we approach?

13 THE COURT: You may.

14 (At sidebar on the record.)

15 MR. O'CONNOR: Your Honor, early on in his testimony
16 he touted the Recovery and what a great filter it was and how
17 there were no problems with it in his practice. That's not a
18 true story. He knows reality.

19 Just now they tried to get in testimony about no
20 literature about struts going to the heart. Well, we know that
21 there have been Recovery filters going to the heart and killing
22 people. His specific question was if there is any literature
23 out there about struts causing death, and he said no.

24 Based upon what he has said about the Recovery, he
25 told this jury, and they went quite a while about it, we think

1 they've opened the door that we should now be able to ask this
2 witness about Recovery deaths.

3 MR. ROGERS: Your Honor, I disagree. I mean, I asked
4 him very specifically about literature about struts going to
5 the heart and causing death. It's in his report.

6 And as Your Honor knows, the jury has heard a lot of
7 evidence from the other side about how she was at risk of
8 sudden death from this. And, Your Honor, it's all specifically
9 addressed in his report. And it's not -- it doesn't have
10 anything to do with cephalad migration death, and I fail to see
11 how there's a connection.

12 THE COURT: Mr. O'Connor, my memory of the cephalad
13 migration death evidence was that they were instances where the
14 entire filter went to the heart, sometimes with a clot burden,
15 that resulted in death.

16 MR. LOPEZ: I think there were some strut fracture
17 deaths too.

18 THE COURT: Well, that's what I'm not remembering. I
19 remember reading instances where it was the whole filter going
20 to the heart causing death.

21 The specific question that was asked of the witness
22 was whether -- and I checked my notes on this too -- whether he
23 was aware of any literature -- I was pretty closely following
24 the language -- showing that a strut going to the heart can
25 cause, I think the question was, specifically, sudden death,

1 which seemed to me to be in response to Dr. Muehrcke's
2 testimony that it can cause sudden death.

3 So would you explain why you think evidence of the
4 entire filter going to the heart is made relevant by that
5 specific testimony of the lack of literature on a strut going
6 to the heart.

7 MR. O'CONNOR: Well, I'd have to go back and look for
8 strut Recovery deaths. As I sit here, I can't tell you that.

9 But I think when you take the context of all the
10 evidence and what they tried to do with this witness, they
11 clearly were getting this witness to talk about how great this
12 Recovery filter was and how great it was in his practice.

13 Now, they have made this guy out to be a foremost
14 expert -- they have made this expert to be a foremost expert.
15 He was a KOL, and so they basically had him come in here --

16 THE COURT: What's a KOL?

17 MR. O'CONNOR: A key opinion leader for Bard.

18 THE COURT: Okay.

19 MR. O'CONNOR: He was a consultant, key opinion leader
20 for Bard. And they brought him in here to talk about what
21 great experiences that his facility had with the Recovery. And
22 I think he knows -- I know that he knows what happened in
23 Recovery. I know that if he is who he says, with the
24 experience he has, he knows of Recovery deaths.

25 I don't think it's fair for us to leave that with this

1 jury without having him to explain that he was aware of
2 Recovery deaths and that that filter was not that good, and, in
3 fact, they stopped selling it.

4 MR. ROGERS: Your Honor, I think I spent a very brief
5 time on the Recovery filter. It's not like I dwelled on it and
6 said it's the greatest filter ever. I mean, we talked about it
7 as far as being the first filter on the market with long-term
8 retrievability, and that's really all I did and moved on. I
9 didn't ask him any questions about the safety on it. You know,
10 it was really focused on the retrievability aspect of it.

11 And in my cross-examination of Dr. Muehrcke, I asked
12 him if he was aware of any literature of a strut from a filter
13 causing a death, and he agreed he was not. So this witness has
14 said nothing different than what their witness has said.

15 THE COURT: Hold on just a minute.

16 So I can't look at this morning's transcript since we
17 have a new reporter and she switched it over, but I've gone
18 through my notes. The only reference I can find specifically
19 to the Recovery filter -- and I've been taking pretty detailed
20 notes -- was when he said that the Recovery filter was -- I
21 don't know what his words he used, but a benefit over the
22 previous filter which had had to be removed every 14 to 21
23 days. It could stay in six months. It was particularly
24 beneficial to trauma patients, I think he said.

25 He did say later that he has used all of the Bard line

1 of filters. I don't think he's focused specifically on the
2 Recovery.

3 My conclusion is that the specific question about
4 medical literature on struts causing heart deaths is directly
5 responsive to Dr. Muehrcke's opinion that the strut going to
6 her heart could cause sudden death and that he hasn't focused
7 on specifically complications with the Recovery.

8 You certainly can, Mr. O'Connor, go into complication
9 rates with the Recovery and the things you've been arguing to
10 the jury about problems with the Recovery, if you want to
11 demonstrate to him or have him agree that there were problems
12 with the Recovery. But I don't think this opens the door to
13 cephalad migration deaths.

14 MR. O'CONNOR: Well, I think we've made a sufficient
15 record, so thank you.

16 THE COURT: Yeah. Okay.

17 MR. LOPEZ: Thank you, Your Honor.

18 THE COURT: Hold it.

19 MR. O'CONNOR: I think that should --

20 THE COURT: I haven't taken anybody's beans today.

21 (End of discussion at sidebar.)

22 THE COURT: Thanks, ladies and gentlemen.

23 MR. O'CONNOR: May I proceed, Your Honor?

24 THE COURT: You may.
25

CROSS-EXAMINATION

BY MR. O'CONNOR:

Q. Hello, Dr. Morris.

A. Good afternoon.

Q. Again, I'm Mark O'Connor.

A. Good afternoon.

Q. How you been?

A. Good.

Q. Dr. Morris, you're here as an expert retained by Bard;
correct?

A. By Nelson Mullins, yes.

Q. But you understand you're testing -- you're testifying on
behalf of Bard Peripheral Vascular and C.R. Bard; you know
this?

A. Yes.

Q. And, regardless, you have been an expert in other cases;
correct?

You serve as expert in other types of cases, do you?

A. Rarely, yes.

Q. And you do know that when you come to court to give
opinions, that your opinions must be accurate and truthful?

You understand that?

A. Yes.

Q. And they must be based upon facts and evidence and other
information; correct?

1 A. Yes.

2 Q. And they must be capable of being substantiated; true?

3 A. Yes.

4 Q. And that means that you rely on the party that retained you
5 to supply you with information that you need to look at to
6 arrive at a fair and truthful opinion; correct?

7 A. Absolutely.

8 Q. That means that you rely on the party that retained you to
9 give information that may help that party; right?

10 A. Yes.

11 Q. But you also expect a complete volume of information,
12 including information that may not be favorable to the side
13 that represents you, that has retained you; true?

14 A. True.

15 Q. So you expect both the good and the bad so that you could
16 evaluate it in arriving at your opinions; right?

17 A. As long as it's reliable, yes.

18 Q. And when you come in here and you tell this jury that your
19 opinions are to a reasonable degree of medical probability, as
20 you did, that's because you are under the impression that you
21 have reviewed all the important information; true?

22 A. Reliable, important information, yes.

23 Q. And in this case, and you have -- you have done a report, a
24 large report, a general report; true?

25 A. Yes.

1 Q. And you've also done a report specific to Lisa Hyde;
2 correct?

3 A. Yes.

4 Q. And in both reports, you understood that you had that
5 obligation to be thorough, to be complete, and to be truthful;
6 right?

7 A. Yes.

8 Q. And to be accurate, so anybody that would review that
9 report or question you about that report could rely that you
10 had looked at all the information possible?

11 A. Just like -- as I treat my own patients, yes.

12 Q. And you received everything you needed from the lawyers
13 representing Bard. That's at least what you assume; true?

14 A. Reliable information, yes.

15 Q. Now, one thing is that, in at least six different places in
16 your report, you identify Lisa Hyde's filter as a Bard G2X;
17 correct?

18 A. I didn't count the number, but that may be true.

19 Q. Okay. You wrote your report about Lisa Hyde's G2X filter;
20 correct?

21 A. Yes.

22 Q. Now, what you have not received are any internal documents
23 from Bard; true?

24 A. Correct.

25 Q. You have not received any documents from Bard or Bard's

1 lawyers that relate to any analysis that Bard did about failure
2 trends within Bard that Bard was aware of; correct?

3 A. Correct.

4 Q. You didn't receive any information from Bard about
5 information Bard was aware about increasing rates of failures
6 with the G2 filter that was not told to doctors; correct?

7 A. Correct.

8 Q. You didn't receive, for example, a G2 caudal report that
9 was prepared by Natalie Wong; right?

10 A. I don't even know who Natalie Wong is. No.

11 Q. You didn't receive a G2 and G2X fracture analysis that was
12 prepared by Bard, did you?

13 A. As long as it wasn't published in the public domain, I
14 would not have seen it, no.

15 Q. It wasn't supplied to you, is my point, from the lawyers at
16 Bard; true?

17 A. True.

18 Q. And you didn't receive documents, for example, on the G2
19 Platinum, did you?

20 A. No.

21 Q. You didn't receive any documents in terms of what Bard was
22 doing by way of alternative designs during the period of 2006,
23 2007, 2008, 2009, did you?

24 A. No interest in that. No.

25 Q. You didn't receive documents from Bard about caudal anchors

1 that explained the reasoning Bard thought that caudal anchors
2 would prevent certain failures, did you?

3 A. No.

4 Q. You didn't receive any type of PowerPoints from Bard or its
5 attorneys that showed that Bard engineers were operating under
6 a hypothesis that if they could eliminate caudal migration,
7 they would also eliminate a high percentage of other failures,
8 including fractures? You didn't receive that, did you?

9 A. No, I did not.

10 Q. You didn't receive a document from Bard that talked about
11 caudal movement and movement that Bard regarded as relating to
12 other failures that wasn't considered to be caudal migration?
13 You didn't receive anything from Bard where Bard was concerned
14 about that, did you?

15 A. No.

16 Q. And you didn't receive e-mails or statements from the
17 medical directors of Bard, did you?

18 A. Not that I'm aware of, no.

19 Q. You didn't receive, for example, an e-mail from
20 Dr. Ciavarella, a medical director at Bard back in December of
21 2005?

22 A. I can't remember that far back, so I do not --

23 Q. You didn't receive an e-mail where Dr. Ciavarella stated
24 that the Simon Nitinol filter had virtually no complaints, and
25 he questioned why wouldn't doctors want to use the Simon

1 Nitinol filter as opposed to the G2 filter? You never received
2 that, did you?

3 A. I don't know about -- I doubt it, but I don't think so. I
4 don't -- I don't know.

5 Q. But what you do know is that the Recovery, the G2, the G2X,
6 and the filters down the line, including the Eclipse, were all
7 cleared and launched and represented by Bard to be permanent
8 filters; right?

9 A. Yes.

10 Q. Now, you had been associated with Bard long before your
11 involvement in this case as a consultant; right?

12 A. Yes.

13 MR. O'CONNOR: As a matter of fact, if we could put up
14 Exhibit 4938.

15 Move for admission of 4938, Your Honor.

16 MR. ROGERS: No objection, Your Honor.

17 THE COURT: Admitted.

18 (Exhibit No. 4938 admitted into evidence.)

19 BY MR. O'CONNOR:

20 Q. You received --

21 MR. O'CONNOR: May I publish, Your Honor?

22 THE COURT: You may.

23 BY MR. O'CONNOR:

24 Q. Here's the point, Dr. Morris. As early as May 18, 2004,
25 Bard was paying you as a consultant to come in and speak on

1 things like the Recovery filter; correct?

2 A. Yes.

3 Q. And you knew about the Recovery filter; true?

4 A. I had experience with it, yes.

5 Q. And you were following the Recovery filter; true?

6 A. What do you mean by following it?

7 Q. You were following the literature about the Recovery filter
8 and how it was behaving in patients across the country --

9 A. Yes.

10 Q. -- correct?

11 And you know that the Recovery was experiencing very
12 serious failures; true?

13 A. We had heard of --

14 Q. Well, I want to be careful here. Can you just answer the
15 question yes or no?

16 A. Okay. Sure.

17 Q. Were you aware of serious failures, serious consequences
18 being caused by the Recovery filter that were being reported?

19 A. Like all filters, I knew that Recovery was --

20 Q. That's not my question. I'm being specific --

21 A. I had no experience.

22 Q. -- about Recovery.

23 A. I had no experience with the failure of the Recovery
24 filter.

25 Q. Let me try it over again.

1 A. Okay.

2 Q. Were you aware -- and I'm only talking about the
3 Recovery -- about serious consequences that were being caused
4 by the Recovery filter during the time that it was on the
5 market, yes or no?

6 A. Yes. I knew about some.

7 Q. By the way, when you were consulting, were you identified
8 as a key opinion leader?

9 A. I have subsequently learned that, yes.

10 Q. And so when Bard would talk about doctors like you, they
11 would refer to you as a key opinion leader. You know that now;
12 right?

13 A. I never heard about that back then, but now I've heard
14 about that, yes.

15 Q. But you knew Bard was retaining your services to help
16 spread the word about its filter products; right?

17 A. I gave several, two or three talks about retrievable
18 filters in general. Bard, Cook, and Cordis were all companies
19 at that time, so --

20 Q. Well, hang on. I just want to talk about Bard filters.
21 I'm going to talk about one person.

22 You remember Janet Hudnall; right?

23 A. Yes.

24 Q. And Janet Hudnall was in marketing; right?

25 A. Yes.

1 Q. And Janet Hudnall, who was in marketing at Bard, is the
2 person that retained you to come in and talk to other doctors
3 about the Recovery filter; true?

4 A. I want to say like three times, and it was not exclusive
5 about the Recovery filter. I want to make that clear.

6 Q. Let me try this again.

7 Janet Hudnall was a person at Bard who retained you to
8 come to different panel meetings and other types of conferences
9 to discuss, among other things, the Recovery filter; true? Yes
10 or no?

11 A. I don't know what you mean by conference. You mean several
12 focus groups? Is that what you're talking about?

13 Q. Yes.

14 A. Yes, we talked -- that was one of the topics at those focus
15 groups, yes.

16 Q. Thank you.

17 Now, I want to talk to you about your testimony
18 earlier when you were talking about an IFU and that statement
19 about recommending patients -- that doctors follow up with
20 patients.

21 Do you recall that testimony?

22 A. Not word for word, but I do remember we talked about the
23 IFU, yes.

24 Q. But that statement in the IFU wasn't about Bard advising
25 doctors and patients that their filter may fail and that's why

1 it came -- that's why they should return; correct?

2 Let me put it to you this way: That statement was in
3 there so that doctors would consider bringing patients who had
4 retrievable filters back to determine whether the retrieve --
5 the filter was still indicated; fair?

6 A. I guess I don't really understand your question. Are you
7 talking about the IFU or --

8 Q. The IFU.

9 A. -- the FDA notice or which?

10 Q. The IFU.

11 A. Okay.

12 Q. You talked about a statement in the IFU.

13 A. I'd have to see the statement. I just can't remember
14 exactly what -- how to put it in the context of your question.

15 Q. There has never been any warning in any Bard IFU that
16 you're aware of that stated that doctors should follow up and
17 monitor patients to look at failures, including perforation,
18 migration, tilt, or fracture; true?

19 A. That's true.

20 Q. Thank you.

21 Now, Doctor, you told us that you're charging \$500 an
22 hour today?

23 A. Yes.

24 Q. But you have charged for your work in this case, which is
25 including preparing an extensive report and a case-specific

1 report; correct?

2 A. Yes.

3 Q. How many hours have you charged Bard for your work for Bard
4 IVC filters?

5 A. I don't know. I haven't counted up the hours.

6 Q. Well, can you give us an estimate today?

7 A. It would be pure speculation. I think -- don't you have my
8 billing sheets? You should know them.

9 Q. Not with me, no.

10 A. Okay. Well, I don't have them with me either. I'd have to
11 count them up.

12 Q. But you've spent several upon several hours, haven't you?

13 A. I've spent several hours, yes.

14 Q. And as a matter of fact, when did you come here to Phoenix
15 to testify? When did you arrive to Phoenix?

16 A. Wednesday around 11:00 p.m.

17 Q. And what are you charging Bard for the time --

18 A. Oh.

19 Q. -- you're spending here?

20 A. Two eight-hour days here.

21 Q. All right. And so how much is that?

22 A. That's 4,000 a day, so that would be a total of \$8,000.

23 Q. And that's what you're expecting to be paid just to come
24 here to court today; correct?

25 A. Yes.

1 Q. And you talked about the Poletti article and the Simon
2 Nitinol filter -- regarding the Simon Nitinol filters before;
3 correct?

4 A. Yes, I have.

5 MR. O'CONNOR: Do you have that exhibit number that we
6 could put up?

7 Do you have it, Felice?

8 Felice, can you go to the conclusion, please? And
9 this is Exhibit 726 -- 7226.

10 No, conclusion. One more page. Trying to get to the
11 conclusion.

12 You had it. Right there. What happened? You had it.

13 MR. LOPEZ: Is that what you wanted?

14 MR. O'CONNOR: Yeah, I want that part, please. Thank
15 you.

16 BY MR. O'CONNOR:

17 Q. Now, one thing that the Poletti article did not show is
18 that when the Simon Nitinol filter fractured, there was no
19 pieces that broke off or embolized to other parts of the body;
20 correct?

21 A. They didn't look for distal embolization, as far as I know,
22 but they didn't mention that, no.

23 Q. And I take it -- and in the Simon Nitinol filter, the
24 conclusion of the Poletti article, the last sentence, do you
25 see that?

1 A. Yes, I do.

2 Q. Could you read that, please?

3 A. Perforation of the vena caval wall, filter fracture, and
4 axial deviation are common but without clinical sequelae.

5 Q. Thank you.

6 Now, let me just talk to you about your opinions
7 regarding Lisa Hyde. First of all, nothing in the Bard IFUs
8 give instructions to doctors as to how to remove a fractured
9 strut from a patient's heart; true?

10 A. True.

11 Q. And you know who Dr. Kuo is, don't you?

12 A. Yes.

13 Q. And Dr. Kuo is one of few doctors that is highly
14 experienced in doing complicated retrievals of filter
15 fragments; correct?

16 A. I wouldn't say it's a few, but he's one of them, yes.

17 Q. Well, I think you told us that you only have done about 200
18 retrievals?

19 A. Of actual retrievals?

20 Q. Yes.

21 A. Yes.

22 Q. And you're talking about retrievals that you've done are
23 the percutaneous retrieval that removes the filter from the
24 vena cava; right?

25 A. That's a retrieval of an IVC filter, yes.

1 Q. But Lisa Hyde underwent that type of retrieval in addition
2 to a procedure to remove the strut from her heart; correct?

3 A. Yes.

4 Q. And Dr. Kuo called that a complex retrieval; true?

5 A. He did, yes.

6 Q. And certainly, Dr. Morris, you have patients of your own;
7 right?

8 A. I sure do.

9 Q. And patients that you have, you meet with and you talk to
10 and you take histories from; right?

11 A. Yes.

12 Q. And you want to know about the patients, when you see them,
13 about their histories of pain and discomfort; correct?

14 A. Yes.

15 Q. And you understand that, as a doctor that works with IVC
16 filters, you're in a select group. Not every doctor across the
17 board, general practitioners, family doctors, or other type of
18 doctors have familiarity with Bard -- with Bard filters or any
19 type of filter like you do; correct?

20 A. Correct.

21 Q. And certainly a reason that you take a history is for you
22 to make a diagnosis and to try to differentiate between
23 symptoms and what may be causing those symptoms; correct?

24 A. Yes. I take the whole picture into consideration.

25 Q. And oftentimes you rely on your patients in your practice

1 to give you a history so that you can help the patient and
2 yourself understand what may be causing a symptom; correct?

3 A. That's one component, yes.

4 Q. What you are not, Doctor -- and I understand it -- you're
5 an interventional radiologist. You're not a neurologist, are
6 you?

7 A. No.

8 Q. And you're not an orthopedic surgeon, are you?

9 A. No.

10 Q. And you understand that those doctors are the type of
11 doctors that can look at nerves and parts of the body that may
12 be susceptible to pain or provide -- produce sensation in a
13 patient; right?

14 A. Yes.

15 Q. And you also understand and have seen cases where patients
16 have had symptoms and it turned out that there was a fractured
17 filter that caused -- was causing the symptoms, it's just
18 simply that doctors were not aware that filters could do that?
19 You've seen those cases?

20 A. Not necessarily, no.

21 Q. All right. Well, do you know what Bard has seen by way of
22 symptomatic versus asymptomatic patients?

23 A. Bard, the company?

24 Q. Yes.

25 A. No. I don't know what they're --

1 Q. You haven't received or reviewed any of the complaint files
2 that Bard has received, have you?

3 A. No, I haven't.

4 Q. And certainly you can understand how there are patients out
5 there who may have Bard filters that have fractures, have
6 tilted filters, have perforating filters, have fractures that
7 have migrated in any -- other places of their body who are
8 unaware of that? You understand that; correct?

9 A. There are patients like that, yes.

10 Q. And unless those patients go see a doctor or have an
11 imaging study, they may not know; correct?

12 A. Imaging study would make the diagnosis, yes.

13 Q. And the point is, there have been no studies to date, have
14 there, that have looked at fragments from filters in patients
15 to determine what may happen to that fragment over a lifetime?

16 A. A lifetime? No.

17 Q. Simply, the medical community doesn't know, do they?

18 A. Like almost all medical devices --

19 Q. No.

20 A. -- true.

21 Q. I'm not talking about medical devices.

22 There's no studies in the medical literature that
23 specifically addresses the problems that struts that fracture
24 and embolize may cause in the future; you're not aware of
25 anything, are you?

1 A. There are studies that have looked at shorter periods of
2 time where they've been symptomatic or not, yes.

3 Q. Nothing in the long term, though; right?

4 A. Well, remember, retrievable filters have only been out for
5 a short period of time, relatively speaking, so how can there
6 be a lifetime of data?

7 Q. Well, I'm not going to debate with you on that.

8 A. Right. I'm just answering your question.

9 Q. I think you and I are on the same page.

10 A. Right.

11 Q. Because of either the timing or whatever, nobody knows what
12 an embolized strut may or may not do to a patient in the
13 future; true?

14 A. Well, we know what foreign bodies do in general. I mean,
15 we have lots of data on the natural history of small metallic
16 structures in the body. Surgical clips, for instance, they've
17 been in the body for at least 40 to 50 years in a lot of
18 patients. We know what the foreign body reaction is to that
19 type of thing --

20 Q. Well, Dr. Morris --

21 A. -- if that's what you're asking.

22 Q. -- my question is specifically about fractured struts.

23 Okay?

24 A. Right.

25 Q. And I think you understand that.

1 There have been no studies on the long-term effect of
2 that; is that true?

3 A. True.

4 Q. Thank you.

5 And you have patients of your own; correct?

6 A. Yes.

7 Q. And you, when you see your patients, patient safety is a
8 priority of yours; correct?

9 A. Yes.

10 Q. And certainly, if you have a patient that would walk into
11 your office who had a fractured strut in her heart, you would
12 be concerned for your patient; true?

13 A. Well, we -- you want me to explain my experience with that?

14 Q. Would you be concerned, yes or no? That's what I want.

15 A. Well, I'm always concerned about every patient, yes.

16 Q. And a strut in a heart, certainly a patient has a right to
17 be concerned about that. You agree with that?

18 A. They should know about it, yes.

19 MR. O'CONNOR: Thank you. That's all I have.

20 THE COURT: Redirect?

21 MR. ROGERS: No, Your Honor.

22 THE COURT: Okay. Thank you. You can step down.

23 (Witness excused.)

24 MR. ROGERS: Your Honor, at this time the defendants
25 call David Feigal.

1 THE COURT: If you want to stand up, ladies and
2 gentlemen, while he's coming in, feel free.

3 THE COURTROOM DEPUTY: Dr. Feigal, if you'll please
4 raise your right hand.

5 (The witness was sworn.)

6 THE COURTROOM DEPUTY: Sir, if you'll please state
7 your name and spell it for the record so the jury can hear it.

8 THE WITNESS: My name is David William Feigal,
9 F-E-I-G-A-L, Jr.

10 MR. CONDO: Thank you, Your Honor.

11 There will come a point in my examination of
12 Dr. Feigal when I'm going to ask him to create a list. May he
13 step down, use the white board, create the list, and then
14 return to the stand to explain?

15 THE COURT: Yeah. If he's going to be testifying
16 while at the white board, let's make sure he has a hand mic.

17 MR. CONDO: Thank you.

18 THE COURT: Otherwise, let's not have him testify till
19 he's back at the mic.

20 MR. CONDO: Thank you.

21
22 DAVID W. FEIGAL, JR., M.D.,
23 called as a witness herein by the defendants, having been first
24 duly sworn or affirmed, was examined and testified as follows:
25

1 DIRECT EXAMINATION

2 BY MR. CONDO:

3 Q. Dr. Feigal, please introduce yourself to the jury and tell
4 us where you live.5 A. My name is David Feigal. I'm an internist, an
6 epidemiologist. I live part time here in Phoenix, in
7 Ahwatukee, and teach at ASU. And most of the time I live in
8 Southern California, just a little bit north of Los Angeles.

9 Q. And what is an epidemiologist?

10 A. Epidemiology is the field of the study of the patterns of
11 diseases in populations. The word originally came from the
12 word "epidemic," because originally people were studying
13 mostly, you know, infectious diseases. But the methods were
14 adapted to study other diseases and adapted to use for studying
15 the safety of medical treatments.16 And so epidemiologists study the patterns, estimate
17 the occurrences, and study the methods. You study these
18 things.19 Q. And what are the tools or methods that epidemiologists use
20 to study?21 A. Epidemiologists study -- are human studies. And so they
22 look at the pattern of diseases, sometimes with studies which
23 are experimental, such as clinical trials; other times they're
24 observational studies, taking a look at what happened in
25 different populations and trying to estimate information about

1 risk factors or safety information.

2 Q. And in this case, what were you asked to do, sir?

3 A. I was asked if I would look at the medical literature about
4 inferior vena cava filters, in particular -- and, in
5 particular, the Bard inferior vena cava filters, and look to
6 see if the information in the literature, the studies of
7 different types, were studies that you could estimate rates and
8 proportions of adverse events that occurred with inferior vena
9 cava filters.

10 Q. And have you formed an opinion on that subject?

11 A. Yes, I have.

12 Q. And was that opinion formed to a reasonable degree of
13 medical and scientific certainty?

14 A. Yes.

15 Q. Let's talk about your training and education that you have
16 in the field of clinical epidemiology.

17 Where did you go to medical school, sir?

18 A. Stanford Medical School in California.

19 Q. And do you have any -- were you a -- you took a residency,
20 didn't you, sir?

21 A. That's right. I did an internship and residency in
22 internal medicine, which is primary care for adults, at the
23 University of California Davis Medical Center in Sacramento.

24 Q. And were you a chief resident at any hospital or teaching
25 facility?

1 A. I was. I was the chief resident after I finished my
2 residency, which was a faculty position, and I remained as the
3 residency coordinator for another year. And then I sought some
4 additional training.

5 Q. And beyond your residency, do you have further education
6 and training?

7 A. Yes. I next went to -- was in a program called the Andrew
8 Mellon Clinical Scholars in clinical epidemiology, which was a
9 joint program between the University of California San
10 Francisco and UC Berkley. So as part of that, I got a master
11 of public health.

12 But I also worked in clinical epidemiology studies at
13 the University Medical Center in San Francisco.

14 Q. And how many years' experience do you have in the field of
15 clinical epidemiology?

16 A. About 40.

17 Q. And in that 40 years, have you consulted on medical devices
18 for various companies?

19 A. I have.

20 Q. And have you taught on the subject of epidemiology and
21 biostatistics at universities or colleges?

22 A. I have. I taught -- I was -- after finishing my
23 fellowship, I became the deputy director of the fellowship
24 program and a member of the faculty at the department of
25 epidemiology, biostatistics, international health, as well as

1 the department of medicine. And I taught there, and I
2 taught -- later I moved to UC San Diego, and I taught the
3 methods there. And in various ways, I've lectured and taught
4 about research methods in epidemiology all over throughout my
5 whole career.

6 Q. And have you practiced medicine?

7 A. Yes. As an internist, I saw patients probably about half
8 of my time, third to half of my time, when I was on the faculty
9 for 12 years at three different university medical centers.

10 Q. Have you ever implanted or retrieved an IVC filter?

11 A. I have not, but I have ordered and -- or requested that a
12 surgeon evaluate a patient for an implantation. So I've had
13 patients of mine who I recommended for an implant where a
14 surgeon did the implant.

15 Q. Would you believe that your lack of experience with
16 implanting or retrieving IVC filters inhibits or limits your
17 ability --

18 (Court reporter clarification.)

19 BY MR. CONDO:

20 Q. Doctor, do you believe that your lack of experience with
21 implanting and retrieving filters inhibits your ability to
22 evaluate the sufficiency of information in the medical
23 literature to determine the rate of adverse events involving a
24 product?

25 A. No. It doesn't inhibit that in any way.

1 Q. And do you still hold an active medical license?

2 A. I do. I've been continuously licensed in the state of
3 California since I was eligible for that in 1977.

4 Q. And have you ever worked for the Food and Drug
5 Administration?

6 A. Yes. I -- after 12 years as faculty at the University of
7 California, I went to the Food and Drug Administration in 1992,
8 and I worked there for the next 12 years.

9 Q. And can you tell us chronologically each of the positions
10 you held over those 12 years at the FDA.

11 A. Sure.

12 So just to back up a little bit, my research area
13 evolved into looking at the clinical epidemiology and clinical
14 trials for the HIV epidemic. I was based at San Francisco
15 General in the '80s. The epidemic came along. We didn't even
16 know what we were looking at when we started.

17 And I got involved with evaluating studies for
18 products, and some of those products were -- became -- were
19 approved by FDA for treatment of infections associated with
20 complications. So that was a large part of my faculty research
21 interest and practice in the late '80s.

22 And so in 1991, the position opened for -- to be the
23 director of the division of antiviral products at FDA, which
24 would give me the sign-off authority on all new products and
25 involvement in the design of the studies and studying the

1 safety of the drugs coming along for AIDS. And at that time,
2 there was only two drugs approved.

3 So even though we were brand new, had just moved to UC
4 San Diego -- my wife had been recruited there -- we picked up
5 and went to Washington for 12 years. And so I worked at the
6 Food and Drug Administration, first in the center for drugs for
7 five years, mostly on drugs relating to infections; and then I
8 was deputy director of the center for biologics, that's blood
9 and vaccines; and then finally I was the director of the center
10 for devices for the last five years that I was in FDA.

11 Q. As a physician and as an epidemiologist, have you conducted
12 medical research studies yourself?

13 A. I have. And actually, I continue to since I've left FDA.
14 I've designed protocols. I've been principal investigator.
15 I've been a statistician on many, many trials.

16 And at FDA, part of our job was to approve studies on
17 investigational products, and so I've been involved in
18 different ways in hundreds, if not thousands, of protocols over
19 the last 40 years.

20 Q. And have you also served as a peer reviewer for journals?

21 A. I have. Mostly when I was still an academic and when I was
22 at FDA, but I was a peer reviewer for the American Journal of
23 Medicine, New England Journal of Medicine, Journal of
24 Controlled Clinical Trials. I've forgotten, actually, which
25 journals since I haven't done much of that in recent years, but

1 that was an active part of my career.

2 Q. And during your career, have you had responsibility for
3 evaluating studies of adverse events associated with drugs and
4 medical devices?

5 A. Yes, I have. I had responsibility for that, actually, with
6 some of the studies that we did at San Francisco General that
7 used medical devices to deliver drugs and we had to file
8 reports to FDA.

9 At FDA, in the drug and biologics center, again, I saw
10 the devices that delivered drugs and those types of things.
11 And then in the device center, the safety people reported --
12 reported to me.

13 And after leaving FDA, I was -- I've primarily been
14 part of a firm that helps start-up companies with their early
15 studies; but for four years I was in industry, and I was
16 responsible for safety departments in -- directly in one
17 pharmaceutical company and shared responsibility in another.

18 Q. And are you being compensated for your time appearing here
19 today?

20 A. Yes, I am.

21 Q. And what is your hourly rate for appearance here?

22 A. My hourly rate is \$650 an hour.

23 Q. And does your rate change depending on whether you're
24 giving testimony or sitting in your office doing research as
25 part of your engagement in this matter?

1 A. No, it's just -- that's just the fee for when I'm actively
2 working on a matter, that plus out-of-pocket travel costs.

3 Q. Can you tell the ladies and gentlemen of the jury the type
4 of medical literature that you reviewed and the work that you
5 did in connection with this case?

6 A. Certainly. There are hundreds of papers written of
7 studies. I looked at the studies that had original data. I
8 also looked at some editorials, but I really was interested in
9 the studies that had original data, because that's where you're
10 going to learn, you know, the primary information.

11 And so you can -- there are search indexes that you
12 can actually use to identify and pull up those papers. And
13 then I got -- you know, I obtained the copies of the original
14 papers. Then when reading the papers, they often would refer
15 other papers, and if those hadn't shown up in my search, I
16 would track those down.

17 So I put together a collection of several hundred
18 papers, of which probably a little less than 200 were really
19 germane to these kinds of topics, were about Bard filters. But
20 I also familiarized myself with some of the literature about
21 other types of filters as well.

22 Q. In addition to the materials that you collected as a result
23 of your own searches, were you also provided information from
24 counsel for Bard?

25 A. Yes, I was. There was some discovery relating to one of

1 the studies, and as part of that discovery there was a
2 deposition and study records that were available, and I
3 reviewed those as well.

4 Q. But from your assignment, did you need to review Bard's
5 internal review, company records, internal reporting rates,
6 fracture analysis, or any of those kinds of materials in order
7 to do what you were asked to do in this case?

8 A. No. That was not what I was asked -- that was not what I
9 was asked to do.

10 Q. But did you get everything from Bard that you asked for?

11 A. Yes, I did.

12 Q. Now, you told the jury that you were asked to look at the
13 published literature to determine whether there was a reliable
14 basis to derive a rate for adverse events from that literature.

15 And have you formed an opinion on that subject?

16 A. Yes, I have.

17 Q. And what is your opinion, sir?

18 A. My opinion is is that if you look at the literature, if you
19 look at the studies that were clinical trials -- and there's
20 very few of those; if you look at the prospective studies where
21 they collected the patients and then followed them forward; if
22 you looked at the studies where they called patients back; if
23 you looked at the studies where they looked at x-ray references
24 and chart reviews, none of them were designed in a way that
25 they could calculate the rates of the occurrence of the events.

1 And so we know that -- what types of events occur, and
2 we know a good deal about individual cases of how some of those
3 occurred, but my opinion is that the medical literature does
4 not provide any information about the rates or the proportion
5 of adverse reactions that occur for common adverse events such
6 as fracture, migration, tilt, embolization. The data just
7 doesn't exist.

8 Q. And is that specific to the Bard G2 filter?

9 A. Yes, it is.

10 Q. With respect to that opinion, do you hold it to a
11 reasonable degree of scientific certainty?

12 A. Yes, I do.

13 Q. Now, let's talk about the tools of epidemiology.

14 First of all, is all scientific evidence created
15 equal?

16 A. No.

17 Q. Is there, in the world of epidemiologists, a hierarchy of
18 scientific evidence?

19 A. There is, yes.

20 Q. And can you step down and explain to the ladies and
21 gentlemen of the jury the hierarchical nature of that evidence?

22 A. Sure.

23 MR. CONDO: May he be permitted to do so, Your Honor?

24 THE COURT: Yes.

25 Mr. O'Connor, if you need to -- or whoever's going to

1 do the cross-examination, if you need to step around into the
2 side of the jury box so you can see this, that's fine.

3 THE WITNESS: So the gold --

4 MR. CONDO: Wait. There needs to be a question first.

5 THE WITNESS: Oh, I'm sorry.

6 THE COURT: Let's turn it just a little bit more this
7 way so Mr. Lopez can see. That's good.

8 BY MR. CONDO:

9 Q. When we talk about a hierarchical nature of studies, what
10 do you mean by a hierarchy?

11 A. Well, there's some studies that are kind of the gold
12 standard that you can rely on because they've been designed in
13 such a way that they remove bias from the studies and the
14 results can be generalized to the population at large.

15 Q. And can you list and write for the ladies and gentlemen of
16 the jury, starting with the gold standard, as you've put it,
17 and descending, the various levels of studies in your
18 hierarchy.

19 A. Sure.

20 Well, at the top of the heap is the randomized
21 controlled trial. So if you're to schematically draw this,
22 you'd have a population that you were drawing people from, and
23 some of them would volunteer to be in the study. And then
24 you'd randomize them, flip a coin. Some would go into one
25 group, some would go into the other group, and then you'd

1 follow them over time. And you'd have planned observations to
2 look for the events that you're looking for until the study was
3 over.

4 And so that has the advantage that it controls -- it
5 makes two groups very comparable, and it has a protocol that
6 sets out all the rules for that. So these are the studies you
7 can really rely on.

8 Q. What is the next study?

9 A. The next group of studies -- all the rest of the studies
10 are observational. They take things that are happening in
11 practice and they take the -- they take a group of patients
12 forward. There may only -- and there -- with these studies,
13 there was most often just a single group that just -- there was
14 just one filter studied, for example.

15 And, again, there would be carefully planned
16 prospective measurements, and at the end they would be able to
17 say what happened. They would have information on everybody,
18 and they would have a protocol and a plan for following that.

19 Q. Would you just label that as a prospective?

20 A. Yeah. This is a cohort study, and it's prospective,
21 meaning that it starts at the beginning and goes forward.

22 MR. LOPEZ: I'm sorry, Your Honor. I didn't hear him.

23 Did you say prospective?

24 THE WITNESS: Prospective, yes.

25 Then there's a similar study that is retrospective.

1 It tries to actually do this study, but it starts at a point in
2 time and they go back and they say, well, what if we go to the
3 radiology department and find the patients who had filters
4 placed or go to the medical records? And so we're going to
5 look back and try and find out what happened back here.

6 And if it's done well, they actually know everybody
7 who got the filter, so that's okay. But not all the
8 information's going to be available because they didn't plan
9 the study in advance, and they don't have any scheduled
10 observations. So not all the patients will even have
11 observations. Some might have one, some might have two. They
12 all have different kinds of follow-up.

13 This is a retrospective, looking back. And often the
14 patients aren't even -- aren't even called in.

15 Now, a variation on that is that they identify
16 patients at a point in time and there's a callback study. And
17 there's a couple of those in the literature where they identify
18 people back here that had filters, and they try and contact
19 them and then they evaluate them out here, you know, with new
20 information collected at that point in time.

21 And there may be some old information but there's no
22 real protocol because they didn't even think of doing the
23 study, just like in the retrospective, until some later point
24 in time.

1 BY MR. CONDO:

2 Q. And what, in descending order, is next on your hierarchy of
3 studies?

4 A. Well, the weakest of the -- the weakest of the studies
5 would be the studies where you have a group of patients at this
6 point in time. You actually have no idea where they came from,
7 but you're studying some issue that they have at that point in
8 time. You're not even necessarily looking at complications.
9 And so these are -- you find these in the retrieval studies.

10 As you know, the filters originally couldn't be
11 removed, or at least not removed very easily. Then they were
12 designed to be removed, and so people would come in for
13 retrieval. And so people at the time of retrieval would say,
14 well, what's the status of the implant in the people who have
15 come in for retrieval?

16 But they often came from multiple different hospitals.
17 They didn't know how many population -- they didn't know -- you
18 know, whatever they were seeing in this, you can't calculate a
19 rate because you don't have that whole group. You don't know
20 who everybody is. You just know the ones that came in to see
21 you, and they may have come to -- they're probably not very
22 representative, particularly if you're a referral hospital
23 because you're particularly good.

24 There are some retrieval studies where they had
25 patients referred because they had a failed retrieval at

1 another hospital. Those patients are going to be a little
2 different. So retrieval studies are a little lower yet on the
3 hierarchy for establishing rates.

4 Q. And now have we completed the hierarchy, or are there any
5 more studies?

6 A. Well, we have one thing left, and that is collections of
7 individual cases. Different hospitals. Different kinds of
8 reports. Sometimes just a single report. We call case
9 reports.

10 And here you don't know anything about the population.
11 You don't know anything about the follow-up. One of the
12 challenges of a rate is that a rate is how something occurs
13 over time. You know, in a mortgage rate, that's how much you
14 pay per year over time. And without the time element -- you
15 increasingly lose the time element in these earlier studies so
16 that you can't calculate this.

17 So it's very challenging from the existing literature.
18 We know what the side effects are. We know how many they saw
19 at some institutions in their studies. But we really can't
20 calculate rates or proportions from the designs because most of
21 the studies are down in these categories.

22 Q. Thank you.

23 MR. CONDO: May he return to the witness chair?

24 THE COURT: Yes.

25 MR. CONDO: Thank you.

1 And while he's doing that, Your Honor, may I mark this
2 for identification as Exhibit 8540?

3 THE COURT: You may.

4 MR. CONDO: Thank you.

5 And by "this," I was referring to the tablet that
6 Dr. Feigal has written on.

7 MR. LOPEZ: I'm sorry. I was moving, Your Honor. Is
8 there an exhibit number to that?

9 MR. CONDO: It is 8540.

10 MR. LOPEZ: Thank you.

11 BY MR. CONDO:

12 Q. Now, if we look at the randomized controlled study --

13 THE COURT: Let's do that after the break.

14 All right, ladies and gentlemen. We will resume at 10
15 minutes to the hour.

16 (Recess taken, 2:33 p.m. to 2:49 p.m.)

17 THE COURT: You may continue, Mr. Condo.

18 MR. CONDO: Thank you, Your Honor.

19 BY MR. CONDO:

20 Q. Dr. Feigal, returning to your hierarchy chart and your
21 opinion that you expressed earlier in your testimony, do the
22 prospective or retrospective studies that appear on your chart,
23 do they -- were they able to provide reliable estimates of
24 IVC -- Bard IVC filter migration?

25 A. No, they were not.

1 Q. Were the prospective, retrospective studies, or the
2 lower-ranked studies able to provide reliable estimates of Bard
3 IVC filter fracture?

4 A. No.

5 Q. And were the prospective, retrospective, or lower-ranked
6 studies able to provide reliable estimates of Bard IVC filter
7 perforation?

8 A. No, they were not.

9 Q. And were the prospective or retrospective or lower-ranked
10 studies able to provide reliable estimates of Bard IVC filter
11 tilting rates?

12 A. No, they were not.

13 Q. And you hold all of those opinions to a reasonable degree
14 of medical certainty?

15 A. Yes, I do.

16 Q. Now, I want to turn to a new subject, if I can.

17 There has been testimony in this case about an article
18 or study referred to as the Nicholson study. As part of your
19 engagement in this matter, were you asked to comment upon the
20 Nicholson study?

21 A. Yes, I was. And I had materials to review that study in
22 quite a bit of detail.

23 Q. Let me just ask you a few very simple questions.

24 First, was the Nicholson study a study of all patients
25 who received Bard IVC filters at the York Hospital?

1 A. No. He said it was in the publication, but in fact, there
2 were 600 filters that were used during the time period of his
3 study, and there were only 189 patients in his study. And we
4 know that he excluded patients from the study who'd had filters
5 during that time period, so it was not a study of all patients.

6 Q. Was the selection of the patients for the study complete --
7 or incomplete and biased?

8 A. In my opinion, yes, it was.

9 Q. And is it important to control for bias in epidemiological
10 studies?

11 A. It is. In other words, if you don't control for bias then
12 the estimates will be too high. They could also be too low,
13 but the kinds of biases introduced by the choices made in this
14 study actually artificially increased the rate but also left us
15 uncertain about what the rates were at all.

16 Q. And did the study protocol lack standard procedures to
17 identify and even contact patients?

18 A. It did. The methods changed during the study, and
19 decisions were made actually not to contact or to include in
20 the study patients who were known not to have filter fractures.

21 Q. As a clinical epidemiologist, can the Nicholson study be
22 relied upon as scientifically reliable, in your opinion, sir?

23 A. No, it cannot.

24 MR. CONDO: Thank you. I have no further questions.

25 THE COURT: Cross-examination?

1 MR. LOPEZ: Yes, Your Honor.

2 CROSS-EXAMINATION

3 BY MR. LOPEZ:

4 Q. Dr. Feigal, good afternoon.

5 A. Good afternoon.

6 MR. LOPEZ: Can I turn this chart towards him, Your
7 Honor?

8 BY MR. LOPEZ:

9 Q. So without going through all these --

10 THE COURT: You need to be talking into the mic. You
11 want the handheld mic?

12 MR. LOPEZ: If I could, Your Honor.

13 THE COURT: Yeah.

14 MR. CONDO: May I move?

15 THE COURT: Yes, you can move over there, Mr. Condo.

16 MR. CONDO: Thank you.

17 THE COURT: Or if you want, Mr. Condo, since he's
18 going to be talking to the jury and the witness, you can come
19 up here.

20 MR. CONDO: Thank you. Excuse me.

21 MR. LOPEZ: May I proceed, Your Honor?

22 BY MR. LOPEZ:

23 Q. So, Dr. Feigal, as far as you could tell from the research
24 that you did, that Bard Peripheral Vascular, C.R. Bard did not
25 conduct, support, or fund any of the studies that are on here;

1 correct?

2 A. Actually, I don't know that. The studies and the
3 literature sometimes -- you know, usually reveal their source
4 of funding. But I would say in general that's probably true.
5 The majority of them were probably investigator studies and not
6 funded, so they were independent of a company.

7 Q. You don't know if they've done a registry or a survey to
8 look retrospectively at any hospital where their devices may
9 have been used to see what the fracture rate is and how many of
10 those fractures went to people's hearts and lungs? As far as
11 you know, none of this exists from anything that Bard has done
12 in the 20 -- 10, 20, almost 30 years that they've had IVC
13 filters on the market; true?

14 A. Again, I'm not sure what Bard has funded, but there has not
15 been a registry. Registries actually enroll people at the time
16 of implantation. They don't look back.

17 But I'm not aware of any studies that were Bard-funded
18 that were registries or other study designs.

19 Q. So if there was room out here, I'd have you come up and
20 draw it.

21 But what we have here -- what we have here from Bard's
22 involvement in the study of their IVC filter devices is the
23 choice they made is below all of these, and that is just to put
24 their device out on the open market to see how it performs.

25 True?

1 A. No, it's not correct. They actually did collect and had a
2 responsibility to collect case reports that were sent directly
3 to them. And so they did have individual case report data.

4 And then, of course, companies -- and I was not asked
5 to review any internal Bard documents, but companies monitor
6 the literature with their products.

7 Q. I think you misunderstood me.

8 I asked you that -- well, let me just follow up with
9 what you just said. In order for them to get these case
10 reports, what is happening out in the open market, Bard's
11 choice was to, instead of doing any of this, was to actually
12 put their device on the market without any clinical evidence of
13 its safety and effectiveness, and just, let's see what happens
14 and see what these reports look like when doctors voluntarily
15 start reporting back to us. True?

16 A. No, that's not true. Would you like me to explain?

17 Q. No. I mean, is there something that Bard did to study the
18 clinical safety and effectiveness of these devices long term
19 before they launched any of them?

20 A. Well, that's a different question than you asked me before.

21 Q. Okay. That's the one I want you to answer right now,
22 please.

23 A. They -- before the studies were approved, prospective
24 studies were done of the G2 and the Eclipse filter. And those
25 were part of the information that were part of the approval

1 process.

2 They were not long-term studies, if you mean that they
3 were longer than a year. But the prospective studies -- there
4 were prospective studies sponsored by Bard that were done prior
5 to putting the products on the market.

6 Q. I'm sorry. But what studies -- what's the name of the two
7 studies you're talking about?

8 A. The first study is the Asch study.

9 Q. Wasn't that a retrievability study to see if the device
10 could be removed?

11 A. No, it was not.

12 Q. Retrieved?

13 A. No, it was not. They did study retrievability as well.

14 Q. Have you looked at the internal documents where Bard is
15 discussing what happened in the Asch study?

16 A. No. It's outside the scope of what I was asked to look at.

17 Q. And do you know what internally Bard was discussing with
18 Dr. Asch and what Dr. Asch says about that study?

19 A. Again, no. I looked at the medical literature, but I was
20 aware that that was a study that was done as part of the
21 approval.

22 Q. Did you see any emails or internal documents that we've
23 seen in this trial already where people that are working at
24 Bard, including one of their marketing people, said we didn't
25 know much, if anything, about the long-term clinical

1 performance of this device when they launched it?

2 You didn't see that?

3 A. That was outside the scope of what I reviewed.

4 Q. Okay. That's what I thought.

5 So now let's talk about the EVEREST study. People
6 have testified already in this court, including some Bard
7 employees, that that study was specific to retrievability. And
8 they did not study patients beyond six months for long-term
9 safety and effectiveness. Did you know that?

10 A. Yes. As I mentioned, the prospective studies usually did
11 not go longer than a year; yes, that's correct.

12 Q. And you mentioned approval process. None of these devices
13 went through an approval process, did they?

14 A. Well, they went through a clearance process, which is what
15 it's called when it's a Class 2 product. FDA calls those
16 clearances rather than approvals.

17 Q. And the truth is that before Bard launched any of these
18 devices, the Recovery filter, the G2, the G2X, and the Eclipse,
19 they had no clinical data about the long-term effects of those
20 devices beyond about six months; true?

21 A. From studies that they were directly involved with, that's
22 true. But there was also the medical literature on the
23 products that were developing as these products were
24 modifications of previous products.

25 Q. I'm not sure I understood that.

1 But the bottom line is that the American consuming
2 public was going to have to answer the question how these
3 devices would perform, what their rates of risk are, what the
4 seriousness of the risks were, by having them implanted in them
5 and hopefully a doctor would report that back to Bard so they
6 could see how their device was performing. True?

7 MR. CONDO: Objection, Your Honor. Argumentative.

8 THE COURT: Hold on just a sec.

9 Overruled.

10 THE WITNESS: It's true that these devices, like many
11 devices, rely on the clinical information from similar products
12 when they're initially launched and that you learn as the
13 product is put in use what the safety profile is of the
14 product; yes, that's correct.

15 BY MR. LOPEZ:

16 Q. Well, don't you think that the people who are getting
17 these --

18 THE COURT: Hold on just a minute. We're going to let
19 Mr. Condo walk back without interrupting you, Mr. Lopez.

20 MR. CONDO: Thank you.

21 THE COURT: Go ahead, Mr. Lopez.

22 MR. LOPEZ: I liked him better over there.

23 THE COURT: You can keep your eye on him.

24 MR. CONDO: Nobody puts Baby in a corner.
25

1 BY MR. LOPEZ:

2 Q. The people that were getting these devices, like Mrs. Hyde
3 and other people that were getting the Recovery, the G2, the
4 G2X, and the Eclipse, don't you think that they should have
5 known that they were going to be the ones that had to answer
6 the question about the safety and effectiveness of those
7 devices long-term for Bard?

8 A. Well, I wouldn't agree with the way you characterized that.

9 Q. Well, I mean, did Bard know something about the long-term
10 effectiveness of their IVC filters by having conducted any of
11 these studies so that they knew what was going to happen to
12 Mrs. Hyde and others that were receiving these devices?

13 A. Well, a company doesn't rely only on the studies that they
14 conduct. And as products are introduced, they're often slight
15 variations on the previous product.

16 Q. Well, for --

17 A. And so they would learn from the experience that they had
18 with previous products what they would expect. They would
19 expect most of the same adverse effects would occur, and these
20 are low frequency events. And so they will learn as the
21 product is put in use how that product performs.

22 But it's not that they don't know anything about it.
23 They just learned from the earlier models and from the medical
24 literature.

25 Q. No, what they were -- they were learning from -- what was

1 going to happen to these people if these devices remained in
2 their bodies for long periods of time and if a doctor would
3 report back to them about what happened after six months, after
4 a year, because Bard couldn't tell anybody what was going to
5 happen with these devices because they hadn't done any of the
6 studies that you listed up here. True?

7 A. No. I disagree with the way you characterized that.

8 Q. Okay. Now, but it is true that Bard has not conducted any
9 of the studies that are listed in your hierarchy from the top
10 to the bottom; correct?

11 A. No. We already talked about how, in fact, there are two
12 studies that --

13 Q. I'm sorry. Let me rephrase the question.

14 They have not conducted any of these studies to answer
15 the question about the long-term safety and effectiveness of
16 any of their devices beyond what we see in the two studies
17 we've already discussed about retrievability. True?

18 A. They have not sponsored those studies, but they had the
19 information from the studies that were being developed in the
20 medical literature and the information on older products. And
21 they knew from the four prospective studies that fracture, for
22 example, was a very low frequency event. Only two cases of
23 fracture in almost 300 patients.

24 Q. Right.

25 A. So they did have information, and this is part of the

1 ongoing process of studying a product during its life cycle.

2 You study it before, you look at the products that were similar
3 to it that were on the market already, and you continue to
4 follow it.

5 Q. Now, sir, would you agree that if you're going to get data
6 to see if your device is performing safety and effectively,
7 instead of just waiting for reports you might or might not get
8 from the voluntary reporting, there are other ways Bard could
9 have gotten more reliable safety information. True?

10 A. I'm not sure -- I mean, it's such -- I'm not sure I can
11 answer that question as a true and false. I mean,
12 hypothetically, yes, there are other methods. And, again, I
13 don't think they relied simply on the spontaneous reports.
14 They looked at all of the studies as well.

15 Q. Now, so Dr. Nicholson, he worked in a hospital. I think it
16 was called York Hospital?

17 A. Yes, that's right.

18 Q. And he was a loyal Bard radiologist; right? That hospital
19 put in a lot of Bard products; correct?

20 A. I don't know.

21 Q. And on his own, Dr. Nicholson and some of his colleagues
22 did a retrospective review of Bard products; true?

23 A. They did what was called a callback study. They identify
24 patients, and 189, as I recall, came in and had fluoroscopy to
25 look at the state of their filter.

1 Q. And that's on the list; right?

2 A. Yes. That is one of the types of studies, yes. A callback
3 study is a retrospective cohort study where you actually
4 interact and contact the patients as opposed to just looking at
5 their charts or their x-rays.

6 Q. And this happened, what, six, seven, eight years after the
7 Recovery filter was on the market and about five years after
8 the G2 was on the market?

9 A. As I recall, it was published in 2010, so he obviously did
10 the studies in the late -- you know, the late 2007, 2008,
11 something in that time period.

12 Q. And Dr. Nicholson did this on his own; right? Bard didn't
13 ask him to do it. No one prompted him to do it. He did it on
14 his own because he thought there might be important information
15 for him to share with the rest of the medical community. Fair?

16 A. Yes. I think he did it on his own; yes, that's correct.

17 Q. And then he conducts this study, and he finds out there's a
18 prevalence of fractures in both the Recovery and the G2
19 filters, including embolization of struts into people's hearts
20 and lungs. And Bard's reaction to Dr. Nicholson doing
21 something they never did was to attack Dr. Nicholson's study;
22 true? Which is what you're doing today.

23 A. Well, I think you asked me about four questions there.

24 Q. Okay. I probably did.

25 But you are aware that Bard's reaction to the

1 Nicholson study, to a physician on his own looking at a patient
2 population because he was concerned about Bard products, was to
3 attack Dr. Nicholson and to try to discredit him?

4 A. I don't think I have any data that would allow me to
5 interpret the state of mind of the company, whether they were
6 attacking or trying to discredit. They had serious questions
7 about the study, and they requested information of the study.

8 And as it turned out, they found out that he grossly
9 misrepresented that study. He did not have rates of
10 prevalence. He did not have incidence. He did not have a
11 finding that multiple implanters had all had a fracture
12 problem.

13 He found that a single physician at York, Dr. Agarwal,
14 had implanted 10 of the 13 products that fractured. No single
15 physician in the literature's ever been published to have had
16 that many complications. So he was really reporting about
17 Dr. Agarwal and Dr. Agarwal's experience with Bard.

18 Without Dr. Agarwal, he had three events. And the
19 embolization patient wasn't even part of his study. He added
20 that in, just as he subtracted out patients who hadn't had
21 filters.

22 So this is a study that actually doesn't meet basic
23 scientific principles of good study conduct.

24 Q. So now eight years later, Dr. Feigal is coming into this
25 courtroom and still attacking Dr. Nicholson's findings. True?

1 A. I don't know if you'd describe it as an attack. I think
2 I'm stating things that are factually correct --

3 Q. All right. Let's --

4 A. -- and which I think he misrepresented in his paper.

5 Q. Let me ask you --

6 A. So I'm correcting the record.

7 Q. All right. Let me ask you, when a medical article does not
8 stand up to the type of scrutiny, the type of protocol that
9 you're talking about, there are other ways to deal with that.
10 You can send letters to the editor. You can do another study.
11 You can have someone go in and look at the data again.

12 That never happened, did it?

13 A. By whom?

14 Q. By anybody.

15 A. No, not to my knowledge. It would have been inappropriate
16 for me to do so since I had seen information that was
17 privileged as part of lawsuits.

18 Q. Well, I mean, those records were still available at the
19 hospital. I mean, they could have hired Dr. Feigal. They
20 could have hired a number of different people who know how to
21 do studies. Dr. Grassi was here earlier today. He's done
22 clinical studies. He's done retrospective studies.

23 They could have hired somebody and said, lookit, we
24 want you to go in and look at this data to see whether or not
25 Dr. Nicholson's findings are actually accurate. They could

1 have done that; right?

2 A. I don't have any direct knowledge of that having been done.
3 My understanding is that the hospital did review the situation
4 with Dr. Agarwal.

5 MR. LOPEZ: Can we look at 587, which was
6 Dr. Nicholson's study, please.

7 BY MR. LOPEZ:

8 Q. And by the way, Dr. Agarwal, do you know anything about
9 him?

10 A. Not very much.

11 Q. Do you know that he was also a loyal Bard customer?

12 A. I don't know anything -- I don't know what you mean by
13 loyal, and I don't know if he purchased those products or if
14 the hospital did. But -- so I can't answer your question.

15 Q. Do you know that actually Bard -- folks from Bard,
16 consultants with Bard, actually trained Dr. Agarwal and others
17 at that hospital on the implantation and the retrieval of their
18 devices. Did you know that?

19 A. I did not. But there is -- there is variation of skill and
20 ability to actually implant these products without damaging
21 them. Not everybody reaches that level of skill.

22 Q. And this idea about skill, there's no evidence in this case
23 about Dr. Agarwal's skill in the placement or retrieval of
24 these devices, is there?

25 A. No. There's just the finding that in over 200 papers,

1 there isn't another report of a single physician -- in fact,
2 most -- there's very few reports and even studies having as
3 many filter fractures as Dr. Agarwal had.

4 Q. Well, how many --

5 Let's look at Exhibit 587. This is the Nicholson
6 study we've been talking about; correct?

7 A. Yes.

8 Q. Published in an authoritative journal. What is it,
9 Archives of Internal Medicine?

10 A. Yes, that's correct.

11 Q. And could we just look at the results section of that,
12 please.

13 And the result of this study, let's just read it. Let
14 me just read it to you.

15 13 of 80 patients had at least one strut fracture
16 (16 percent). At least one strut in seven of the 28 Bard
17 Recovery filters fractured and embolized (25 percent). In five
18 of these seven cases, patients had at least one fragment
19 embolize to the heart.

20 Did I read that correctly?

21 A. You did. But I think the study --

22 Q. 71 percent?

23 A. Yes. But I think the study misrepresents what actually --

24 Q. I understand what your opinion is. I'm just reading what
25 Dr. Nicholson's writing.

1 A. Yes, that's what he wrote.

2 Q. Three patients experienced life-threatening symptoms of
3 ventricular tachycardia and/or tamponade -- tamponade --

4 A. Tamponade.

5 Q. Tamponade, including one patient who experienced sudden
6 death at home.

7 Did I read that correctly?

8 A. You did.

9 Q. 6 of 52 Bard G2 filters fractured (12 percent).

10 Did I read that correctly?

11 A. You did.

12 Q. In two of these six cases, the patients had asymptomatic
13 end organ fragment embolization.

14 Explain what that "end organ fragment embolization"
15 means. Does that just mean a piece of that fragment went to a
16 distant part of the body?

17 A. Yes, that's what that means.

18 Q. Now, there's been no evidence as far as you know that, as
19 described, that this is not accurate information; true?

20 A. Well, there is evidence. He did not include all of the
21 patients --

22 Q. No, sir. As reported, these fractures, just the way these
23 are described, whether or not he included other people, these
24 are real findings of real problems in real people that happened
25 in one hospital as reported by Dr. Nicholson; correct?

1 A. The number of fractures is correct. The proportions are
2 not.

3 Q. Okay. And then Dr. Nicholson actually --

4 MR. LOPEZ: Can I have 3924, please?

5 BY MR. LOPEZ:

6 Q. The Nicholson study is still cited. It hasn't been taken
7 down. It hasn't been retracted. It's still in the medical
8 literature to be cited in other medical literature; true?

9 A. That's correct.

10 Q. And Dr. Nicholson -- do you see where I'm looking at there?

11 In June --

12 A. Yes.

13 Q. -- of 2012, in the same journal, he wrote: Corrections to
14 article about prevalence of fracture and fragment embolization
15 of Bard retrievable vena cava filters.

16 Correct?

17 A. Yes.

18 Q. You didn't write a letter to the editor, did you?

19 A. No. I wouldn't --

20 Q. No other interventional radiologist, no one else who read
21 this article, no other physician who had an interest in IVC
22 filters wrote a letter to this journal criticizing or saying
23 anything about this article. True?

24 A. I don't know if there's other articles criticizing other
25 things, but this is information only known to Dr. Nicholson and

1 which he learned during a deposition when the information was
2 presented --

3 MR. LOPEZ: Move to strike, Your Honor.
4 Nonresponsive. He's going -- he's giving a narrative that's
5 beyond what I asked him.

6 THE COURT: Hold on just a minute.

7 Why don't you reask the question. The first part of
8 his answer was responsive.

9 BY MR. LOPEZ:

10 Q. Let's just go to Dr. Nicholson's letter to the -- in
11 correction of his article.

12 We are writing to inform the readers and editors of
13 the Archives that we have discovered errors in our article
14 titled "Prevalence of Fracture and Fragment Embolization of
15 Bard Retrievable Vena Cava Filters and Clinical Implications,
16 Including Cardiac Perforation and Tamponade."

17 The 189 patients described in the published study were
18 identified from general surgery and interventional radiology
19 logs and were a subset of all patients who underwent
20 implantation of vena cava filters between 2004 and 2009.

21 Did I read that correctly?

22 A. Yes, you did.

23 Q. Despite requesting complete patient lists from each
24 division, a log of radiology patients who received the Bard G2
25 filter -- and it says Bard Peripheral Vascular -- at York

1 Hospital between 2007 and 2009 was not made available to
2 investigators, and therefore, these patients were not included
3 in the fluoroscopy study.

4 Did I read that correctly?

5 A. That's correct. The logs he was provided by his own
6 hospital were incomplete.

7 Q. It only included the time period 2004 to 2000 -- to maybe
8 2006 or '7; right?

9 A. Yes. He had -- yes.

10 Q. All right. Now, a copy error in Figure 2 incorporate --
11 incorrectly stated that 83 patients agreed to fluoroscopy. The
12 correct number is 80.

13 Did I read that correctly?

14 A. You did.

15 Q. As reported in the text abstract and statistical
16 calculations of the article. In Table 2, four different
17 physicians implanted filters which went on to fracture, with
18 ten of these devices implanted by the same physician.

19 Did I read that correctly?

20 A. You did.

21 Q. While these issues do not have significant bearing on the
22 results reported in our study and do not change our
23 conclusions, we thought that they should be disclosed.

24 William J. Nicholson, Department of Cardiology, York
25 Hospital.

1 Did I read that correctly?

2 A. You did.

3 Q. Actually, the percentages should have been a little bit
4 higher, because instead of the denominator being 83,
5 Dr. Nicholson is saying the denominator's 80; true?

6 A. No. The denominator's 189.

7 Q. But they did 80 fluoroscopies instead of 83; correct?

8 A. That's correct. Out of the -- but --

9 Q. All right.

10 A. -- again, it does not include the patients that he already
11 knew did not have fractures. He just excluded those and didn't
12 include them. So his numbers are still not correct, even with
13 his corrections.

14 Q. Now, let me ask you, part of epidemiology and the science
15 that you practice, you don't just look at one piece of evidence
16 to determine whether or not there is something there; right?
17 You look at other evidence, even if it's low-value evidence,
18 because you don't have this higher level of evidence. True?

19 A. That's correct. You consider it all.

20 Q. Okay. Now, did Bard show you their internal tracking and
21 trending of the same type of events that Dr. Nicholson
22 describes in his study?

23 A. The scope of my report was to review the medical
24 literature, and that's what my report was about. In response
25 to information in Bard -- in plaintiffs' experts, who cited

1 spontaneous report data, I also had additional data provided by
2 Bard about spontaneous reports.

3 Q. So you didn't know when you were doing this analysis that
4 Bard had in its complaint files 355 total fractures of the
5 Recovery through Eclipse filters as of July 2010, did you?

6 A. I'd have to go back to see the records to see what was
7 there, but they are not records -- I mean, my task was to
8 calculate the incidence and prevalence of different types of
9 fractures, and that information is not -- you can't get that
10 information from that. So I --

11 Q. You didn't have it. That's all I'm trying to find out.

12 A. No, I think I may have had it. I was supplied some
13 information, but I didn't rely on it because it couldn't
14 actually provide information about what I was asked to do.

15 Q. I'm talking about looking for things that are consistent
16 with what you looked at in the literature.

17 How many of those 355 fractures during that period of
18 time were what Bard calls Type A fractures?

19 A. I don't -- I don't know. Again, I did not rely on the --

20 Q. Sir --

21 A. -- on that single report, so I did not try and analyze them
22 in any way.

23 Q. Do you know what a Type A fracture is as defined by Bard?

24 A. No, I do not.

25 Q. Do you know what a Type B fracture is as defined by Bard?

1 A. No.

2 Q. Do you know how those Type A and Type B fractures compare
3 to other filters that were on the market at the same time with
4 respect to their reporting risk rate?

5 A. Well, there aren't any reliable reporting risk rate
6 calculations.

7 Q. You didn't do any; right? You didn't do any reporting risk
8 analysis, did you?

9 A. The information to do reporting risk rates is not
10 available, so I wouldn't have done them. But it was, again,
11 beyond the scope of what I was asked to look at. I was asked
12 to look at the medical literature.

13 Q. Doctor, do you know who Natalie Wong is?

14 A. I'm not sure.

15 Q. Do you know that Natalie Wong did a statistical analysis of
16 the adverse events as they relate to Recovery and other filters
17 that were on the market?

18 A. I don't recall.

19 Q. Do you know who Dr. John Lehmann is?

20 A. I do not recall.

21 Q. Do you know that Dr. -- that Natalie Wong was still an
22 employee at Bard while the Recovery filter was only on the
23 market for a short period of time, did a statistical analysis,
24 and determined that there was a statistically significant
25 increased risk of fatalities with the Recovery filter in the

1 first several months it was on the market compared to a number
2 of other filters including its predicate device, the Simon
3 Nitinol filter? Did you know about that?

4 A. I've seen those analyses. I was -- did not consider them
5 in my calculations because I didn't think that the statistics
6 and the calculations they were doing were valid and could be
7 relied upon.

8 Q. Did you see the statistical analysis that it was reported
9 by a Dr. John Lehmann, who is --

10 A. I don't recall.

11 Q. Do you know who Dr. Lehmann is?

12 A. I don't recall.

13 Q. Do you know that he's an epidemiologist from Harvard?

14 A. I don't -- I don't recall ever having -- recall who
15 Dr. Lehmann is.

16 Q. Do you know that Dr. Lehmann concluded, and it was reported
17 in one of their health hazard evaluations, that the Recovery
18 filter was four to five times more likely to cause perforation,
19 migration, fracture, tilt, and catastrophic injuries, more so
20 than any other device on the market at that time? Did you know
21 that his analysis concluded that?

22 A. I'm not sure if I ever saw that. But, again, if it's based
23 on spontaneous reports and comparisons across reports, that's
24 exactly the kind of comparison that FDA themselves says you
25 can't use this information to do that. It's not reliable.

1 Q. It's the only data that Bard left us with, isn't it?
2 Because they didn't do any of these other things for us to
3 evaluate. We're stuck with that safety data, aren't we?

4 A. No. We have the whole body of the medical literature which
5 is reported on the experience of these products in thousands of
6 patients, and we have the experience of the reports of studies
7 with different, you know, strengths and weaknesses. And as you
8 pointed out, we consider it all. We don't just limit ourselves
9 to the spontaneous reports and try and make mathematics out
10 of --

11 Q. Do you know whether or not the findings in -- that
12 Dr. Nicholson has and that these other people we just talked
13 about had with respect to their statistical analysis was
14 consistent with the bench testing that was done by Bard on
15 these products?

16 A. I was not asked to evaluate the bench testing.

17 Q. You just looked at these articles and the data and said
18 there's just -- we just don't have anything that's going to
19 allow anyone to really know how bad or how good Bard IVC
20 filters are once they're implanted in patients; true?

21 A. No, that's not correct. The medical literature is
22 available to all physicians. It describes the spectrum of
23 complications that occur. It describes how to treat them.
24 Describes how to retrieve filters, how to retrieve difficult
25 filters. It describes case reports of individual patients.

1 All of that is kind of clinical information clinicians
2 need for risk-benefit. What it doesn't do is it doesn't give
3 you a rate. You can't say that it's a rate or proportion.

4 Q. Right. And you know that this case is about whether or not
5 these rates, whatever they are, may have been increased by
6 design deficiencies that Bard acknowledged they had in some of
7 their devices? Did you know that that was what this case was
8 about?

9 A. I understood that that was an issue in this case, yes.

10 Q. And whether or not the rate increases 10 percent,
11 20 percent, or 30 percent, wouldn't you agree that if that was
12 caused by a design defect, that the first thing that Bard ought
13 to do is fix the design to lower whatever that rate might be?
14 Don't you agree with that?

15 MR. CONDO: Beyond the scope.

16 THE COURT: Sustained.

17 BY MR. LOPEZ:

18 Q. Now, you, in prior testimony -- I'm just going to ask you
19 this question and see if you answer it the same.

20 One of the primary reasons companies cannot use
21 adverse events to state that "This is our failure or
22 complication rate" is because you don't know whether there were
23 10 or a hundred times that this same event happened in other
24 patients where it was just not recorded; true?

25 A. Yes. That's the phenomenon of --

1 Q. Is that true, Dr. Feigal?

2 A. Yes. That's underreporting, and I acknowledge that that's
3 an issue with the reports. That's why you can't calculate
4 rates from --

5 Q. Doctor, I want you to please answer this question whether
6 or not it's true or false: A responsible and ethical company
7 should -- what a responsible and ethical company should do, in
8 the interest of patient safety, is to assume that they're only
9 seeing the tip of the iceberg when doctors are reporting these
10 fractures that are migrating to the heart and lung and other
11 complications that Bard filters are having.

12 A. Yes, I agree with that. And what companies do is they look
13 at each of those cases individually and say, what do we learn
14 from this case and is there something we can do to mitigate
15 this case, which could involve changing the device, could
16 involve better training. That's what companies do.

17 Q. Now, I want you to assume that if -- assuming you've sold a
18 hundred Bard filters, and among those hundred, you get one
19 report of a serious injury. Would it be misleading for someone
20 to say that the unreported cases are evidence of a 99 percent
21 success rate?

22 A. I don't know if I have enough information from your
23 hypothetical to answer that.

24 Q. Well, what happens if they're not reported? If you
25 don't -- if you don't know anything about the other 99 because

1 no one's telling Bard about them, they're not reporting it to
2 them, they don't know what happened with those devices? They
3 don't know whether or not they stopped a PE or didn't stop a
4 PE; true? No one's reporting that; right?

5 MR. CONDO: Beyond the scope, Your Honor.

6 THE COURT: Sustained.

7 BY MR. LOPEZ:

8 Q. Now, Doctor, would you agree that the reason you look for
9 safety signals once a device is on the market, especially if
10 there have been no long-term clinical trials for safety, is to
11 find out whether or not something unexpected or unintended is
12 happening with your product so that you can take steps to
13 protect people from those risks; true?

14 A. Yes.

15 Q. And adverse events give the company a first hint that they
16 may have a design issue with their product. You would agree
17 with that?

18 A. They can. Not always, but that's one of the ways that you
19 look at the design.

20 Q. And you've actually made public statements in your career
21 that there are times a single case can identify a design issue.
22 True?

23 A. That is true.

24 Q. Do you know that Bard -- do you know whether Bard had
25 actually acknowledged that they had design issues with their

1 Recovery, their G2, their G2X, and Eclipse filter just based on
2 signals they were getting from doctors that were implanting
3 these?

4 A. Again, I wasn't really asked to look at anything internal
5 to Bard or what their conclusions were.

6 Q. And you were not provided with documentation based on these
7 adverse events and the company's risk analysis that included
8 that the G2 filter posed an unacceptable risk of serious harm
9 to patients; true?

10 A. It was outside the scope of my report. I don't know if
11 I've seen documents like that in depositions of other -- of
12 other experts, but it was not something that was -- that I
13 considered in my report and whether you could calculate rates
14 or proportions.

15 Q. And you were not provided with documentation that, based on
16 that analysis, they should not launch the product into the open
17 market until they fixed the problem? You weren't provided with
18 that data, were you?

19 A. Again, that was not a question that I was asked to review
20 and was not part of the scope of what I was asked to be an
21 expert about.

22 Q. And you didn't look at any internal documents that
23 discussed the design -- the design deficiencies and how the
24 correction of those design deficiencies would significantly
25 reduce the type of event that happened to Mrs. Hyde as a result

1 of having a G2X implanted in her; true?

2 A. I was not asked to offer opinions about the design, and I
3 did not ask for documents about the design.

4 Q. Doctor, you would agree that whether we know what the exact
5 rate is, whether the -- well, let me ask you this question:
6 Every time we look at a number, a statistic, we're talking
7 about real human beings; right?

8 A. Absolutely.

9 Q. We're talking about people --

10 A. Yes.

11 Q. -- correct?

12 A. Absolutely.

13 Q. So if Bard has 200 people by 2010 who have had this thing
14 migrate to their heart, pieces migrate to their heart, they
15 shouldn't -- should they say, well, let's see if we can
16 statistically justify not taking that device off the market?
17 They shouldn't do that; right?

18 MR. CONDO: Objection. Beyond the scope, Your Honor.

19 THE COURT: Sustained.

20 MR. LOPEZ: Those are all the questions I have, Your
21 Honor.

22 THE COURT: Redirect?

23 MR. CONDO: Yes, Your Honor.

24 MR. LOPEZ: Actually, Your Honor, I do have -- I have
25 one more document I want to show Dr. Feigal. I apologize.

1 Exhibit 1212, please.

2 BY MR. LOPEZ:

3 Q. Dr. Feigal, you recognize this article; correct?

4 A. Yes. I wrote this at the request of Guidant Corporation
5 with two other -- with two cardiologists. I'm not a
6 cardiologist.

7 Q. And it was published in the New England Journal of
8 Medicine?

9 A. That's correct.

10 Q. And this is an article that you wrote in 2006; correct?

11 A. I think -- yes, that's correct.

12 Q. And let's look at this real quickly. Let's look at -- the
13 title is what?

14 A. "Life-Threatening Malfunctions of an Implantable Cardiac
15 Device."

16 Q. Okay. And I'd like to direct your attention to the last
17 page of this article. And if you look at the first column,
18 where it says, "In the past."

19 Do you see where I am?

20 A. Yes.

21 Q. And you wrote: In the past, this industry -- and you're
22 talking about the medical device industry; correct?

23 A. That's correct.

24 Q. The medical device industry involving implantable cardiac
25 devices; correct?

1 A. Yes.

2 Q. This industry has not had a good record of open
3 communication, but transparency does benefit companies that
4 want to be viewed as trusted partners in the healthcare
5 enterprise. As the panel noted, transparency may be passive,
6 with information made available to those who seek it; active,
7 with information targeted to specific groups of stakeholders;
8 or forced, with a third party bringing forth information that
9 elicits further disclosure by a company as a defensive move.

10 Did I read that correctly?

11 A. Yes.

12 Q. From the perspective of physicians' and patients'
13 expectations, corporate responsibility, and public perception,
14 we believe that proactive communication policies centering on
15 the proper use of active and passive transparency should be the
16 norm.

17 Did I read that correctly?

18 A. Yes, you did.

19 Q. Insofar as such communication is hindered by perceived
20 business conflicts, the solution may lie in new regulatory
21 definitions that distinguish informational actions from those
22 that indicate the removal of a device.

23 Did I read that correctly?

24 A. You did.

25 Q. Changing language can be difficult since much of it is

1 embedded in statutory requirements.

2 Did I read that correctly?

3 A. You did.

4 Q. Now, let's go down to -- just down in that same column.

5 And right at the very bottom, it says: "With the explosive
6 growth of the industry."

7 Do you see where I am?

8 A. Yes.

9 Q. In recent years, previously unrecognizable signals have
10 become increasingly visible. Clearly, strategies for
11 evaluating and communicating device malfunctions must be
12 adjusted accordingly. Our conclusion is that industry should
13 work collaboratively with physicians, professional societies,
14 patient representatives, and regulatory agencies to establish
15 reasonable standards and guidelines for the device industry to
16 follow. Patients deserve nothing less.

17 Did I read that correctly?

18 A. You did.

19 Q. And you still believe that today; correct?

20 A. I do.

21 MR. LOPEZ: All right. Those are all the questions I
22 have, Your Honor. Thank you for letting me do that.

23 THE COURT: Redirect?

24 MR. CONDO: Yes, Your Honor. Thank you.

1 REDIRECT EXAMINATION

2 BY MR. CONDO:

3 Q. Dr. Feigal, you were asked a series of questions about the
4 number of fractures attributed to Dr. Agarwal in the Nicholson
5 study?

6 A. Yes.

7 Q. How many fractures were attributed to Dr. Agarwal?

8 A. 10 of the -- 10 of the 13 patients who had fractures were
9 implanted by Dr. Agarwal.10 Q. And can the skill and technique of the implanter contribute
11 to a complication rate?

12 MR. LOPEZ: Your Honor, beyond the scope. He's --

13 THE COURT: Overruled. It's not beyond the scope.

14 MR. LOPEZ: Then I'm going to object based on
15 foundation and --16 THE COURT: I think there does need to be foundation
17 for this question.

18 BY MR. CONDO:

19 Q. As part of your epidemiological training, do you look at
20 factors which can influence complication rates?

21 A. Yes.

22 Q. And is human factor, the human factor in an event, one of
23 those elements that you look at to determine whether or not it
24 influences a complication rate?

25 A. Yes, it is. And here --

1 MR. LOPEZ: I'm going to object. He's going to launch
2 into a narrative that may include something I might want to
3 object to.

4 THE COURT: Well, if he does, you can object.

5 MR. LOPEZ: Pardon me?

6 THE COURT: If he does, you can object.

7 THE WITNESS: And problems caused by human errors,
8 even when there's nothing wrong with the device, are reportable
9 adverse events to the FDA.

10 BY MR. CONDO:

11 Q. So let me ask the question again. Like all surgical
12 procedures, are there human factors that may contribute to the
13 complication rate depending on the skill and technique of the
14 operator implanting an IVC filter?

15 MR. LOPEZ: Your Honor, objection. Foundation.

16 THE COURT: Overruled.

17 THE WITNESS: Yes.

18 MR. CONDO: Thank you. I have no further questions.

19 THE COURT: All right. Thanks. You can step down,
20 Doctor.

21 (Witness excused.)

22 MR. ROGERS: Your Honor, at this time defendants call
23 Rob Carr.

24 THE COURT: Mr. Carr, you can come directly back to
25 the witness stand since you're still under oath for purposes of

1 this trial.

2 ROBERT MICHAEL CARR JR.,
3 called as a witness herein by the defendants, having been
4 previously duly sworn or affirmed, was examined and testified
5 as follows:

6 DIRECT EXAMINATION

7 BY MR. ROGERS:

8 Q. Good afternoon, Mr. Carr.

9 A. Good afternoon.

10 Q. Can you remind the jury, please, of what your full name is?

11 A. Robert Michael Carr Jr.

12 Q. And can you remind the jury how long you've worked at Bard.

13 A. Almost 20 years. 22 years.

14 Q. What division of Bard do you work for?

15 A. Peripheral Vascular.

16 Q. And what sort of products does that division make?

17 A. We make mostly implantable devices, either some vascular
18 stents, we make a lot of balloon angioplasty devices, we have a
19 full biopsy -- cancer biopsy line, vena cava filters. Those
20 sorts of things.

21 Q. And so, Mr. Carr, are you an engineer by training?

22 A. I am, yes.

23 Q. Can you tell the jury about your educational background.

24 A. I have a Bachelor of Biomedical Engineering at Catholic
25 University in Washington, DC.

1 Q. And can you describe for us what is biomechanical -- or
2 biomedical engineering?

3 A. So it's really a combination of -- at Catholic was a
4 mechanical engineering curriculum with kind of a pre-med or
5 nursing curriculum.

6 Q. So what led you into that field?

7 A. Just interest in sciences, mostly, and then -- and also
8 engineering, so thought I would be a doctor one day but was
9 just a nice major.

10 Q. And since you finished with that degree, have you been
11 working in the medical device industry pretty consistently
12 since then?

13 A. Only since then, yes. Fully.

14 Q. And so what was your first job after you left school, when
15 you got your degree?

16 A. I was an entry level engineer at a company called
17 Organogenesis, which was in Boston, Massachusetts.

18 Q. And what types of products did that company make?

19 A. We made skin, actually. So a professor from MIT determined
20 a way to grow human skin from certain cells. And we then sold
21 those products to cosmetic companies to do testing on as well
22 as to some burn victims for skin replacement.

23 And then I worked specifically on products that were
24 made from collagen, which is a natural protein in your body.

25 Q. And did there come a point where you left that company and

1 went to a company called NMT?

2 A. Yes.

3 Q. And so what positions did you hold at NMT?

4 A. I started as the director of R&D at NMT, and when I left to
5 go to Bard, I was a program director.

6 Q. What does NMT stand for?

7 A. Nitinol Medical Technologies.

8 Q. And while you were at NMT, what product did you spend the
9 majority of your time on?

10 A. Vena cava filters.

11 Q. And when you started working with vena cava filters, what
12 types of filters were on the market at that time?

13 A. There were only permanent devices at that time.

14 Q. And can you describe for the jury, as far as the filters
15 that were at NMT, what were they made of?

16 A. They were made of a material called Nitinol.

17 Q. And the jury's heard a little bit about Nitinol, but can
18 you describe for us what that is?

19 A. So Nitinol is a pretty cool material. It's what's called a
20 shape memory material. Whereas at one temperature it can be
21 one shape and you can form it into that shape, and then you can
22 program it by cooking it in an oven to then form at a different
23 shape at a given temperature.

24 Q. And so can you tell the jury, though, what happens if the
25 Nitinol is then changed to a different temperature, once it's

1 forged into a shape?

2 A. So as I said, so, for example, our filters primarily start
3 as a series of straight wires. And then they're wound around
4 what we call a jig, or a three-dimensional object. We put that
5 in an oven at a given temperature for a given amount of time,
6 remove it from that jig, and if you cool it down, it can go
7 back to being those straight wires. If you heat it up, it will
8 form into the shape of a filter in that case.

9 Q. So does it essentially remember the shape in which it is
10 forged?

11 A. Yes. Shape memory.

12 Q. And so did you work some at NMT with a doctor named
13 Dr. Morris Simon?

14 A. Yes, very much.

15 Q. And can you tell the jury who he is?

16 A. So he was the founder of NMT, or Nitinol Medical
17 Technologies. He was a world-renowned interventional
18 radiologist in Boston at a very famous hospital there, Beth
19 Israel Hospital.

20 Q. And is that the person that Simon Nitinol filter is named
21 for?

22 A. It is.

23 Q. And did you work with Dr. Simon in regard to the Simon
24 Nitinol filter?

25 A. Not in the original development of it, but later while I

1 was there, we actually transferred the manufacturing of that
2 device into NMT. We had contracted somebody to make it for the
3 first few years it was made.

4 Q. And did you and Dr. Simon work on the development of a
5 retrievable filter?

6 A. Yes.

7 Q. And what filter was that?

8 A. What ultimately became the Recovery filter. There were
9 many iterations prior to us being successful and making the
10 Recovery.

11 Q. What led you and Dr. Simon to try to develop a retrievable
12 filter?

13 A. So, really, it was his idea. You know, being an
14 interventional radiologist who saw tremendous amount of
15 patients and being an inquisitive guy, he knew that while
16 permanent filters, his own especially, provided a great benefit
17 to patients, that they really needed one that was able to be
18 taken out. Most patients don't need a vena cava filter
19 forever. They need it for an undisclosed period of time.

20 And so his idea was could we develop a filter that
21 could stay in permanently or could be removed when it was
22 needed -- or no longer needed.

23 Q. In addition to Dr. Simon, did you work with other
24 interventional radiologists in the development of the
25 retrievable filter?

1 A. Yes, we had several we worked very closely with. John
2 Kaufman was one primarily. He was at Massachusetts General
3 Hospital at the time. He's now at the Dotter Institute in
4 Portland, Oregon. And another, Tony Venbrux is his name. He
5 was at Johns Hopkins University in Baltimore.

6 Q. And so what was the atmosphere like at NMT about the
7 possibility of this retrievable filter?

8 A. So it was exciting. An incredibly collegial atmosphere.
9 Brilliant minds of these physicians and the other people who
10 were there, with an opportunity to do something, frankly,
11 nobody else had ever done. Being a 20-something-year-old out
12 of school, it was an incredible place to be.

13 Q. Mr. Carr, at some point did NMT sell the rights to the
14 Recovery filter to C.R. Bard?

15 A. Yes. The Recovery and the SNF.

16 Q. And did you eventually move to Bard?

17 A. I did, in 2002.

18 Q. And is that what brought you to the Phoenix area?

19 A. It is, yes.

20 Q. And you've been in Phoenix ever since then?

21 A. I have been.

22 Q. And so when you were working at Bard, did you have an
23 opportunity to continue to work on this same project?

24 A. Yes.

25 Q. And so what was your title or your capacity in that regard?

1 A. I started as the program director of R&D for our vena cava
2 filter programs; our angioplasty program, which is balloons
3 that open up your vessels; and as well as our biopsy products
4 at the time.

5 Q. And were there other engineers that came over from NMT to
6 Bard in addition to you?

7 A. Yes. About probably 18 months later, I brought one of our
8 principal engineers named Andre Chanduszko from NMT to Bard.

9 Q. And as part of your continued work on the development of
10 this filter, did you continue to work with Dr. Kaufman and
11 Dr. Venbrux?

12 A. Yes, we did.

13 Q. Mr. Carr, I want to kind of change gears on us and talk
14 about just the general development of a new medical device and
15 what that entails.

16 MR. ROGERS: And, Scott, would you mind pulling up
17 Exhibit 6089?

18 BY MR. ROGERS:

19 Q. And do you see that on your screen, Mr. Carr?

20 A. I do.

21 Q. And is this a PowerPoint presentation?

22 A. Yes, it is.

23 Q. And is it something that you helped prepare as part of your
24 work at Bard?

25 A. I did make this, yes.

1 MR. ROGERS: Your Honor, I move this into evidence.

2 MR. O'CONNOR: Hold on. I don't know that we received
3 that.

4 Oh, I'm sorry.

5 Your Honor, I've been told this has been not -- this
6 document has not been produced.

7 MR. ROGERS: Your Honor, it's my understanding it has.

8 THE COURT: Not produced when?

9 MR. LOPEZ: As part of discovery.

10 MR. O'CONNOR: It has no Bates number.

11 THE COURT: All right. Let's talk about that at
12 sidebar.

13 You can stand up, ladies and gentlemen.

14 (At sidebar on the record.)

15 THE COURT: What's your objection?

16 MR. O'CONNOR: Well, nondisclosure.

17 THE COURT: Did you preserve that objection in the
18 final pretrial order?

19 MR. LOPEZ: Pardon me?

20 THE COURT: Did you preserve that objection in the
21 final pretrial order? Did you make the objection to the
22 document in the final pretrial order? I required you to
23 indicate all your objections to all exhibits.

24 MR. LOPEZ: I thought we were reserving that to trial.

25 THE COURT: Well, that's why we got the long list of

1 exhibits and objections in the final pretrial.

2 MR. LOPEZ: I know, but this was never produced to us
3 in discovery.

4 THE COURT: Well, the point is if it was in the final
5 pretrial order, you should have listed that as an objection.

6 And I said when I adopted the final pretrial order, any
7 objections not contained in the final pretrial order are waived
8 unless you can make a showing of manifest injustice.

9 MR. LOPEZ: I thought we were reserving those for when
10 they were offered at trial. That was my understanding of the
11 Booker trial and --

12 THE COURT: I didn't --

13 MR. LOPEZ: In other words, there's --

14 THE COURT: My order specifically says you have to
15 list objections to exhibits.

16 MR. LOPEZ: But I thought -- I may be wrong, Your
17 Honor, but I thought because there were going to be 8,000 of
18 these, that we were reserving the right to make those
19 objections when they were -- any of them were being offered.
20 Otherwise we'd spend six months going through documents
21 objecting to them.

22 THE COURT: That's why I suggested before Booker that
23 you reduce the size of your exhibit list, was for that reason.

24 Am I misunderstanding what your understanding is?

25 MR. ROGERS: No, Your Honor.

1 MS. HELM: We did objections.

2 MR. O'CONNOR: Pardon me?

3 MS. HELM: We did objections to exhibits.

4 MR. LOPEZ: I know, but if something's not produced in
5 discovery --

6 THE COURT: Then you should object in the final
7 pretrial order. That's the whole point of it.

8 MR. LOPEZ: All right. Well, we can talk about that
9 later, but obviously it's not this trial. But it's impossible
10 for us to do that.

11 THE COURT: Well, you've never said that before just
12 now, and we're in the middle of our third bellwether trial.

13 MR. LOPEZ: I know. This is the first time it's
14 happened where I see something that wasn't produced in
15 discovery.

16 THE COURT: Was this produced in discovery?

17 MR. ROGERS: I genuinely do not know the answer, Your
18 Honor. But what I do know is that this document was used in
19 another federal case that was tried, not one of the MDL --

20 THE COURT: Well, but that doesn't answer the
21 question.

22 MR. ROGERS: No, and I told you I don't know the
23 answer.

24 THE COURT: Was it used in Booker or Jones?

25 MR. LOPEZ: The Phillips trial?

1 MS. HELM: Yes.

2 MR. ROGERS: Yes.

3 MS. HELM: And those trial transcripts and exhibits
4 have all been produced.

5 MR. LOPEZ: I can't say -- I can't say anything other
6 than the fact -- what prompted me, there's no Bates numbers on
7 here. So I don't know whether this was dated --

8 MS. HELM: That happens a lot with PowerPoints. When
9 you regenerate them, Bates numbers don't come off, so we have a
10 number of exhibits --

11 THE COURT: Well, it sounds like I can't decide
12 whether or not it was produced in discovery and I can't decide
13 whether or not it was objected to in the final pretrial order
14 because we don't know sitting here. So I don't think I have a
15 basis for excluding it.

16 MR. LOPEZ: I'm sure it was --

17 MR. O'CONNOR: What are you going to use it for?

18 MR. ROGERS: We're going to look at one slide, which
19 is going to be fairly innocuous.

20 (End of discussion at sidebar.)

21 THE COURT: Thank you, ladies and gentlemen.

22 Exhibit 6089 is admitted.

23 (Exhibit No. 6089 admitted into evidence.)

24 MR. ROGERS: Thank you, Your Honor. May we display it
25 to the jury, please?

1 THE COURT: You may.

2 BY MR. ROGERS:

3 Q. Mr. Carr, you have the document on your screen?

4 A. Yes, I do.

5 MR. ROGERS: And, Scott, if you wouldn't mind taking
6 us to the third page, please.

7 BY MR. ROGERS:

8 Q. And, Mr. Carr, is this a slide that you helped develop
9 while you were at C.R. Bard?

10 A. Yes. I created this slide.

11 Q. And can you describe for the jury, just generally to begin
12 with, what does this slide -- what is it about?

13 A. So it's a pictorial representation of our product
14 development process, so how we go about through what's called a
15 phased approach of developing our products.

16 Q. And let's -- if you don't mind, I'm going to walk through
17 the phases with you.

18 And the first thing that we see there is -- I guess in
19 that first circle on the left-hand side, it says Idea Generation
20 Process. Can you tell the jury what that means?

21 A. So we generate ideas. So before a product or an idea can
22 be thought of, we do a lot of research, experiential, being --
23 talking with physicians, being in cases, reading literature,
24 whatever it may be. And we try and identify what's called an
25 unmet need, and then we try and develop solutions to unmet

1 needs.

2 And so in this process, it's kind of a time where we
3 can just think of solutions to ideas or to needs and develop
4 different prototypes and things like that that ultimately, one
5 day, hopefully, reach a point where they're worth considering
6 to move on further, to invest in, both in people and money.

7 And so the Idea Phase.

8 Q. All right. And the next bubble or circle, I guess, it says
9 Concept Phase. What happens during that phase?

10 A. So that's really where a tremendous amount of work is done
11 to really put a lot of meat around that unmet need, to validate
12 the assumptions that go into that need, be they monetary, be
13 they material, can you make it, is it actually needed, you
14 know, what patients does it serve.

15 All of the work to develop a working prototype and a
16 working, in this case, device that would then be worth testing
17 in feasibility and what's called development later.

18 Q. All right. And so I guess we've kind of gone through the
19 Feasibility and Development Phase.

20 And then you've got sort of a different thing there
21 that says Launch, in between Development and Post Launch. Tell
22 us what that means.

23 A. So I think before we get to Launch, we should talk about
24 the arrows below, which is the reviews. So none of these
25 phases are moved past until you have a very significant review

1 by independent people at the company from different walks of
2 life, be they engineering, marketing, sales, et cetera, where
3 the team presents their data at the time to then get approval
4 to move forward across that process.

5 If you successfully move through Concept, Feasibility,
6 Development, there is another review that is done prior to
7 submission to the -- in our case, the FDA. And then
8 ultimately, hopefully, Launch.

9 Q. And then the final circle on the right says Post Launch.
10 Can you describe that for the jury please?

11 A. Yes. So at a period of time after the product's been on
12 the market, we review manufacturing data, so did we make it for
13 the cost and the time that we thought we would. We walk
14 through any complaints that may have happened through that
15 time. We go out and see cases and get a general sense for how
16 the product was doing.

17 And then we have a design review again to ensure that
18 we want to continue with that product commercially.

19 Q. And when you were at first NMT and then at C.R. Bard, was
20 this general product development cycle, was that followed by
21 you in the development of IVC filters?

22 A. Yes. This process is generally followed by all device
23 manufacturers.

24 Q. All right. So, Mr. Carr --

25 MR. ROGERS: You can take that down, please, Scott.

1 Thank you.

2 BY MR. ROGERS:

3 Q. I want to talk to you a little bit about the development of
4 the Recovery filter. But before I do that, I want to back up
5 and ask you just some general questions about filters.

6 The jurors have heard some references through the
7 trial about conical filters. Can you describe for us, please,
8 what that means? What is a conical filter?

9 A. So a conical filter is one that is cone shaped, so that
10 generally at the bottom of the filter, or towards the legs,
11 would be the widest part, and it would move up into a cone
12 shape.

13 Q. And so are there particular advantages of a conical design
14 for a filter?

15 A. There are dramatic advantages, yes.

16 Q. And what are those?

17 A. Mostly, the way the filter traps clot. So that when you
18 have a clot burden, if it were to be trapped by the filter, a
19 conical filter allows that clot to move to the center of the --
20 in this case, vena cava. And it leaves the most surface area
21 for the rest of the blood to flow through. Versus if it were
22 the opposite way, if the tip of the cone was facing down, the
23 clot would move to the outside, and that would actually tend to
24 cause the vessel to thrombose, potentially.

25 Q. And are you generally familiar with the design of

1 competitor companies' filters that are on the market?

2 A. Yes.

3 Q. And so of the competitor filters, how would you describe
4 how many, from a percentage standpoint or what's easiest for
5 you to describe, how many are conical filters?

6 A. They are all conical filters except for one called the
7 Bird's Nest, which is a -- looks like a nest. It's for very,
8 very large vena cava where other filters don't work. So
9 it's -- everybody has kind of one of them on a shelf for that
10 kind of patient.

11 But, generally, every other filter is conical in
12 shape.

13 Q. And was the Simon Nitinol filter a conical filter?

14 A. Yes. The bottom half of it is conical.

15 Q. And are you familiar with a filter called the OptEase
16 filter?

17 A. Yes.

18 Q. Is it a conical filter?

19 A. It is, with the noted exception that it is one of the
20 filters that the cone faces outward.

21 Q. And is that the difference, as far as being a conical
22 filter, between the OptEase filter and the Bard filters?

23 A. That's one of the differences, yes.

24 Q. And so would the Bard filters, would they be considered
25 inward cone-shaped IVC filters?

1 A. Yes.

2 Q. And that would be different from the OptEase because it's
3 an outward shaped cone filter; is that right?

4 A. At the bottom of it, yes.

5 Q. And so what are some of the advantages or disadvantages of
6 having a filter which is an inward cone-shaped filter versus
7 one that is an outward cone-shaped filter?

8 A. So like I said, the primary one is the ability to trap clot
9 and move it to the center of the vessel. What that also does
10 is it allows the flow or the velocity of the blood going past
11 it to be faster and potentially break up the clot, is one of
12 the things people think about, versus the outward one. And
13 again, like I said, it would tend to be more thrombosing.

14 Q. And when you say thrombosing, what do you mean by that?

15 A. Well, just that the clot on the outside would fill the
16 vessel faster than the same volume of clot if it were in a
17 cone -- an upward cone shape.

18 Q. And can thrombosis lead to something called occlusion of
19 the IVC?

20 A. Yes.

21 Q. And tell the jury what that is, please.

22 A. So it would be where you have so much mass in the vessel
23 that blood flow is no longer going past the filter and the
24 clot.

25 Q. Let's talk specifically about the development of the

1 Recovery filter.

2 Can you tell the jury approximately when the process
3 started to develop the Recovery filter?

4 A. The first ideas were in 1996.

5 Q. And so how many prototypes did NMT go through in the
6 development process?

7 A. A bunch. A half a dozen, probably.

8 Q. And why were some of the prototypes rejected, ultimately?

9 A. Well, ultimately they would have failed one test or
10 another, either they couldn't be deployed properly or they
11 didn't perform well in a certain bench test or in an animal
12 test, for whatever reason. There were various reasons and
13 various designs that were tried.

14 Q. And approximately when was the initial design of the
15 Recovery filter complete?

16 A. 1999 time frame.

17 Q. And the Recovery filter was cleared by FDA approximately
18 when?

19 A. As a permanent device, in 2002.

20 Q. All right. Let's talk about some of the testing that was
21 performed on the Recovery filter when it was being developed.

22 Can you describe generally for the jury the types of
23 tests that would have been performed on that filter?

24 A. So we do what's called bench testing, so in the lab where
25 we can control certain parameters we want to test.

1 We do animal testing where we implant, in this case,
2 the filters into animals and see how they -- the vessel
3 responds as well as could we remove the device and what damage,
4 if any, that might have caused.

5 And then, ultimately, we did a clinical trial.

6 Q. And speaking of clinical trials, when you were at NMT, was
7 a clinical trial performed on the Simon Nitinol filter?

8 A. Before I was there, yes.

9 Q. And do you know approximately how long that clinical trial
10 lasted?

11 A. Those patients were followed for 180 days.

12 Q. So that's approximately about six months?

13 A. Yes.

14 Q. And for the Recovery filter, did you do a long-term
15 randomized clinical trial?

16 A. Ultimately, for Recovery we did a special access study in
17 Canada.

18 Q. But as far as doing -- before the product went on the
19 market, was any long-term clinical trial done in human beings?

20 A. Yes. Those -- that study, those patients were followed out
21 to 180 days.

22 Q. And let me be clear about -- just because the term
23 "long-term" has obviously got some subjectivity to it.

24 But did the company do a study that would have lasted,
25 let's say, 5 years, 10 years, or 20 years as a clinical study

1 in humans?

2 A. No, we did not.

3 Q. And why is that? Why was such a study not performed?

4 A. Because it's not practical. So if you studied something
5 for that long, first of all, our intention was for filters to
6 be removed. So the time after that, they were followed to 180
7 days, which was what permanent filters -- the prior permanent
8 filter clinical trial that we did was.

9 To follow a device for 10 or 20 years or a patient for
10 10 or 20 years, that device wouldn't be on the market today.
11 It never would have seen the light of day.

12 Q. And what would generally happen to the technology for that
13 filter if you were doing a study that lasted 10 years to 20
14 years?

15 A. Well, it might have gone nowhere because it never -- it
16 would have just been in study forever. But, you know, you have
17 to balance the study time versus the value that it provided to
18 patients.

19 Q. All right. Mr. Carr, let's talk about the testing that was
20 done on the Recovery filter and also the provision of that
21 testing to the FDA.

22 MR. ROGERS: Can we pull up Exhibit 5189, please.

23 BY MR. ROGERS:

24 Q. And, Mr. Carr, do you see that?

25 A. I do, yes.

1 Q. And can you tell the jury what that document is?

2 A. It is a 510(k) submission for the Recovery filter in 2002.

3 MR. ROGERS: And, Your Honor, we move this document
4 into evidence.

5 MR. O'CONNOR: No objection.

6 THE COURT: 5189 is admitted.

7 (Exhibit No. 5189 admitted into evidence.)

8 MR. ROGERS: May we display?

9 THE COURT: You may.

10 BY MR. ROGERS:

11 Q. And, Mr. Carr, if you could, can you remind the jury what
12 exactly a 510(k) application is?

13 A. So it's the submission that we give to the FDA. It's our
14 regulatory pathway to get our devices -- this type of device on
15 the market.

16 MR. ROGERS: And, Scott, if you could go to page 18 of
17 that document, please.

18 And can you pull out the -- I guess the sort of middle
19 part? Yeah. Thank you.

20 BY MR. ROGERS:

21 Q. Okay. So, Mr. Carr, can you describe for the jury what
22 we're seeing here?

23 A. This is a summary of the modifications to the filter on the
24 left-hand column. And then the tests that were performed on
25 the right-hand column.

1 Q. All right. And let's just kind of walk through some of
2 these, if you don't mind.

3 The first thing that's listed there is Clot Trapping
4 Efficiency. What is that?

5 A. So it is the ability of the filter to trap or hold clot
6 from going past it.

7 Q. And the next thing we see is something called Migration
8 Study. What is that?

9 A. So that's the pressure required to dislodge a filter from
10 where it was placed.

11 Q. And below that is Weld Integrity. What is that?

12 A. That is a test of the strength of the filters assembled --
13 there's 12 wires that are welded together thermally with heat,
14 and so we test the strength of that bond.

15 Q. All right. And below that is Hook Strength. What is that?

16 A. It is the force that is required to pull the hook,
17 straighten the hook out. The way our filter is developed is
18 the hook is -- enters the vessel wall and there is a force that
19 is able to straighten that hook out because it is Nitinol, and
20 that's what allows it to be removed from the vessel.

21 Q. All right, sir. And the next is Corrosion/Fatigue Testing.
22 Can you describe that?

23 A. So it's a material test that shows whether the filter
24 corrodes in the body in a salt or aqueous environment. And
25 then the fatigue testing is how many cycles can the filter move

1 before it breaks, like if you took a paper clip or something
2 like that.

3 Q. All right, sir. And then below that is Radial Strength.
4 What kind of test is that?

5 A. So that measures the outward force that the filter places
6 on the vessel. So the elements of the device, and you measure
7 how hard they push out.

8 Q. All right. And below that we see Spine Glue Joint Tensile
9 Test. What is that?

10 A. It's a strength test where we -- several pieces of what we
11 call the delivery system, the piece that helps the filter get
12 where it's going, there's things that are glued together or
13 welded together, and we break them apart.

14 Q. And so -- and the last thing that's in that box is
15 Simulated Use Study. What is that?

16 A. So we try and simulate the use of the filter in a given
17 environment. So be they animal studies or whatever they may
18 be.

19 Q. All right. Let's go to page 21, please.

20 And so, Mr. Carr, can you describe for us what we're
21 seeing here.

22 A. This is a description of the migration study and the
23 results.

24 Q. And let's go on to the following page, 22.

25 And is that the continuation of the description?

1 A. Of the summary, yes.

2 Q. All right. And then on to 23, please.

3 A. So this is, again, another outline of the weld integrity,
4 which we talked about, hook strength.

5 Q. All right. And then on to page 24.

6 A. And this is the corrosion and fatigue testing.

7 Q. And so what is the purpose of these descriptions for FDA?
8 What are you providing them?

9 A. An outline of what the test was and then ultimately the
10 results of those tests.

11 Q. All right. And let's go on to page 25.

12 And so what do we see here?

13 A. Our radial strength summary.

14 Q. On to page 26.

15 And what is that?

16 A. Simulated use testing.

17 Q. All right. And then let's go on to page 29, please.

18 And as far as the tests that we have seen earlier that
19 are described, what is the information that you provide to FDA
20 about those tests, just in general?

21 A. We provide them the protocols in the reports, so the
22 results of the testing.

23 Q. And, Mr. Carr, the jury's heard that that type of
24 information or tests are not submitted to FDA. In this
25 process, did you submit your test results to FDA in this 510(k)

1 application?

2 A. Yes.

3 Q. All right. Now, let's look at page 29. And this says
4 Clinical Experience.

5 And so what is this information that is being provided
6 to FDA?

7 A. This is a summary of the special access study I referred to
8 that we were doing in Canada.

9 Q. And does this go on for several pages?

10 A. Yes, it does.

11 MR. ROGERS: All right. And, Scott, if you would, go
12 to page 33, please.

13 BY MR. ROGERS:

14 Q. And this particular page, is this a continuation of the
15 information that was provided to FDA about the study that was
16 done by Dr. Murray Asch in Canada?

17 A. Yes.

18 Q. And so what is the information we're seeing here about
19 Patient 9 and Patient 33?

20 A. For Patient 9, there was a noted or an observed migration
21 when we were going to remove the filter. So that's described
22 here.

23 Q. All right. And so what's the information that's being
24 provided about Patient 33?

25 A. It's a -- oh, 33, I'm sorry. That there was -- in this

1 patient, that there was an observation of a filter fracturing
2 in the arm; and then upon removal, it was noticed that one of
3 the hooks had also fractured.

4 Q. And so was that information laid out for FDA?

5 A. Yes, in this document.

6 MR. ROGERS: All right. We can pull that down,
7 please, Scott. And let's go to page -- excuse me, to
8 Exhibit 5187.

9 And, Your Honor, I move this document into evidence.

10 MR. O'CONNOR: No objection.

11 THE COURT: Admitted.

12 (Exhibit No. 5187 admitted into evidence.)

13 MR. ROGERS: May we display?

14 THE COURT: You may.

15 BY MR. ROGERS:

16 Q. All right. Mr. Carr, can you tell the jury what this
17 document is, please?

18 A. This is a letter from the FDA back to us with questions on
19 our submission.

20 Q. And so we won't go through all of the questions, but
21 looking down at the bottom, it says Clinical Testing. Do you
22 see that?

23 A. Yes.

24 Q. And was that some of the subjects that FDA had questions
25 about, was about the clinical testing?

1 A. Yes.

2 MR. ROGERS: All right. And, Scott, can you take that
3 down, and let's go to the next page.

4 BY MR. ROGERS:

5 Q. And so here, is this a list of questions that the FDA had
6 about bench performance testing?

7 A. Yes, it is.

8 Q. All right, sir. And there we see on the page how many
9 questions from FDA?

10 A. Seven.

11 Q. Yes, you're correct. It starts at 3. It's late in the
12 day, Mr. Carr. Thank you.

13 All right. Following page, 3, please.

14 And is that a continuation of the questions that the
15 FDA had that we see there at the top of the page?

16 A. Yes, it is.

17 Q. And did the FDA also have questions about biocompatibility?

18 A. They did.

19 Q. And then below that, did the FDA have questions about
20 administrative elements?

21 A. Yes, they did.

22 Q. All right. And next page.

23 And so there were a total of 17 questions that the FDA
24 asked Bard about the submission that Bard gave to FDA?

25 A. Yes.

1 Q. And so, Mr. Carr, what did Bard do in response to these
2 questions?

3 A. We reviewed them and did whatever was necessary to provide
4 answers, and then we did provide written answers to them for
5 all of the questions.

6 MR. ROGERS: All right. Can you take that down,
7 Scott? Thank you.

8 And can you pull up Exhibit 5182.

9 And, Your Honor, we move this document into evidence.

10 MR. O'CONNOR: I think, Your Honor, we're agreeing to
11 admission and subject to some objections about parts of this
12 exhibit that we have notified the other side about.

13 THE COURT: Has there been some agreement on
14 redactions?

15 MR. ROGERS: I'm unaware.

16 MS. HELM: There have been, Your Honor.

17 THE COURT: All right. I'll admit it subject to the
18 redactions you discussed.

19 (Exhibit No. 5182 admitted into evidence.)

20 MR. ROGERS: Okay, thank you.

21 BY MR. ROGERS:

22 Q. And so, Mr. Carr, can you tell the jury generally what this
23 is?

24 A. This is our response letter to those questions.

25 Q. And were you involved in the preparation of the responses

1 to FDA to their 17 questions?

2 A. Yes.

3 Q. And so what types of things -- and we're not going to get
4 into the specifics of these question by question, but what
5 types of things did Bard tell FDA in response to some of their
6 questions?

7 A. We answered their questions directly, so whatever they may
8 have been, we -- whether we did testing or just answered them
9 from knowledge or clarification. They were of all different
10 kinds.

11 Q. And did you go through just individually question by
12 question?

13 A. Question by question, yes.

14 Q. All right, sir. And can we go to page 30 of this document.

15 And was this part of that same response? Was this
16 part of what went back to FDA?

17 A. Yes.

18 Q. And can you tell the jury what we're seeing here.

19 A. This is a test report that was done on the cyclical
20 polarization for the filter, the Nitinol.

21 Q. All right. And was that one of the things that you felt
22 like FDA needed to see in order to answer all of their
23 questions?

24 A. Yes. They had a specific question on it.

25 MR. ROGERS: And, Scott, would you mind going to

1 page 118.

2 BY MR. ROGERS:

3 Q. And, Mr. Carr, what is this?

4 A. This is a test report for our simulated use testing that
5 was done.

6 Q. And was this sent to FDA in response to their questions?

7 A. Yes, it was.

8 Q. And so can we go to now page 127.

9 And what is this, Mr. Carr?

10 A. It is a procedure for the weld integrity testing.

11 Q. All right. And was that provided to FDA in response to
12 their questions?

13 A. Yes, it was.

14 Q. All right. And now how about page 132.

15 And what is this we see here?

16 A. It's the report for that weld integrity testing.

17 Q. So were you providing the FDA both the protocol and the
18 actual test report?

19 A. Yes.

20 Q. All right. Let's go to page 140.

21 And what is this, Mr. Carr?

22 A. It is the test report for the hook strength testing.

23 Q. And that was provided to FDA in response to their
24 questions?

25 A. Yes.

1 Q. All right. And how about page 153.

2 And what is this, Mr. Carr?

3 A. It is the procedure for the radial strength testing.

4 Q. And so is all of this information that we have seen here
5 about Bard's testing, was this all provided to FDA in response
6 to their questions about the Recovery filter?

7 A. Yes, it was.

8 Q. And so, Mr. Carr, once this information was sent to FDA,
9 did you receive a response from FDA?

10 A. Yes. They had a few more questions.

11 MR. ROGERS: And if we could pull up Exhibit 5179,
12 please.

13 And, Your Honor, I move this into evidence.

14 MR. O'CONNOR: No objection.

15 THE COURT: Admitted.

16 (Exhibit No. 5179 admitted into evidence.)

17 MR. ROGERS: May we publish?

18 THE COURT: Yes.

19 BY MR. ROGERS:

20 Q. And, Mr. Carr, is this what FDA sent back? Is that right?

21 A. Yes, it is.

22 Q. And let's look at something just as a "for example" here.

23 MR. ROGERS: Can we pull out number 1, please? And
24 that's a little lopsided, I guess. It may not be fixable. Try
25 it again, Scott.

1 Okay. Thank you.

2 BY MR. ROGERS:

3 Q. And so just in general, Mr. Carr, so the jury gets a sense
4 of it, so what is FDA asking of Bard after it's received the
5 testing reports and protocols that we just took a look at?

6 A. This was a clarifying question on the clot trapping that we
7 did.

8 Q. All right. And so after FDA asked more questions, what was
9 the next step in the process?

10 A. We responded to them.

11 MR. ROGERS: All right. And can we take this down,
12 please, Scott?

13 And can you pull up Exhibit 5178.

14 And, Your Honor, I move this into evidence.

15 MR. O'CONNOR: Excuse me. No objection.

16 THE COURT: Admitted.

17 (Exhibit No. 5178 admitted into evidence.)

18 MR. ROGERS: May we display?

19 THE COURT: You may.

20 BY MR. ROGERS:

21 Q. And, Mr. Carr, is this the letter that went back to FDA
22 regarding the additional questions that they asked?

23 A. Yes, it is.

24 Q. And so again, just for an example, can we pull out Question
25 No. 1?

1 And, Mr. Carr, does that just repeat the question that
2 FDA asked?

3 A. Yes. We state the question and then the answer.

4 MR. ROGERS: Okay. And so, Scott, would you mind
5 taking that down?

6 And then let's go to the answer. And so -- I think
7 it's really just the whole page, if you don't mind.

8 BY MR. ROGERS:

9 Q. And so as an example, again, Mr. Carr, is this the type of
10 thing that you provided FDA information about?

11 A. Yes, it is.

12 Q. All right. And so what happened after Bard responded to
13 these questions that FDA posed?

14 A. They sent us a letter concurring with our submission.

15 MR. ROGERS: All right. And can we pull up
16 Exhibit 5177, please.

17 And, Your Honor, I believe this is in evidence. May
18 we display?

19 THE COURTROOM DEPUTY: It is.

20 THE COURT: You may.

21 BY MR. ROGERS:

22 Q. And, Mr. Carr, is this the letter where FDA cleared the
23 Recovery device for a permanent indication?

24 A. It's the letter where they concurred with us, yes.

25 Q. All right. Thank you.

1 MR. ROGERS: And, Scott, you can take that down.

2 Thank you.

3 BY MR. ROGERS:

4 Q. And, Mr. Carr, did Bard submit an additional 510(k)
5 regarding the Recovery filter for retrievability?

6 A. Yes, we did.

7 MR. ROGERS: All right. And can we pull up
8 Exhibit 5169R, please.

9 And, Your Honor, I move this into evidence.

10 MR. O'CONNOR: No objection.

11 THE COURT: Admitted.

12 (Exhibit No. 5169R admitted into evidence.)

13 MR. ROGERS: Your Honor, may we display?

14 THE COURT: You may.

15 BY MR. ROGERS:

16 Q. And, Mr. Carr, is this the 510(k) application that was
17 submitted to FDA for the clearance of the Recovery device as a
18 retrievable filter?

19 A. Yes, it is.

20 Q. And, Mr. Carr, do you know generally approximately how
21 large this submission is? I mean, I know we can just see pages
22 on the screen, but can you give us some idea of how big this
23 document is?

24 A. It's probably 2 or 3 inches tall.

25 Q. And, Mr. Carr, did the -- what type of information was Bard

1 providing FDA about this retrievable indication?

2 A. Any additional bench testing, animal testing, and our
3 clinical trial testing for -- to support the retrievability of
4 the filter specifically.

5 Q. And did FDA ultimately clear the Recovery filter for a
6 retrievable indication?

7 A. They did.

8 MR. ROGERS: All right. And can we pull up
9 Exhibit 5197, please.

10 And, Your Honor, I move this into evidence.

11 MR. O'CONNOR: No objection.

12 THE COURT: Admitted.

13 (Exhibit No. 5197 admitted into evidence.)

14 MR. ROGERS: May we display?

15 THE COURT: You may.

16 BY MR. ROGERS:

17 Q. And so, Mr. Carr, is this the clearance letter from FDA of
18 the Recovery filter for retrievable indication?

19 A. Again, it's their concurrence letter to us, yes.

20 Q. Okay. Thank you.

21 Mr. Carr, let's move forward a little bit in time, and
22 let's talk about the G2 filter. And the jury's heard a lot
23 about both the Recovery filter and the G2 filter. What's the
24 relationship between those two devices?

25 A. The G2 was the next generation removable vena cava filter

1 for us.

2 Q. And when did you start your work on the development of the
3 G2 filter?

4 A. 2004 or '5.

5 Q. And so why did Bard start developing the G2 filter?

6 A. We looked for ways we could improve the current device.
7 We're always looking to replace ourselves in the market and
8 improve the device. We call it the total product life cycle,
9 if you will.

10 Q. And what were the specific attributes of the device that
11 you wanted to work on to try to improve its performance?

12 A. The migration resistance of the filter and the fracture
13 resistance of the filter.

14 Q. And when you say migration resistance, the jury's heard
15 about migration, but we've also heard about caudal migration
16 and cranial migration.

17 So, first of all, what is cranial migration?

18 A. It is movement upward or towards the heart.

19 Q. And if we talk about caudal migration, what type of
20 movement is that?

21 A. Down towards the legs.

22 Q. And so the design changes that were made from the Recovery
23 filter to the G2 filter to try and address migration, what was
24 the type of migration that you were trying to address?

25 A. Cranial migration.

1 Q. All right. Let's talk some, Mr. Carr, about the various
2 tests that were performed on the G2.

3 And let me ask you first, did you conduct animal
4 studies on the G2 filter?

5 A. Yes, we did.

6 Q. And what types of animal studies did you do?

7 A. So we essentially repeated the animal study we did for
8 Recovery where we implant the filters into the animals. At
9 given time points we look at them while they're still in place,
10 and we also, at another time point and a different set of
11 animals, remove those filters and see what effect they may or
12 may not have had on the vessel after they were removed.

13 Q. And what types of animals would these filters be implanted
14 in?

15 A. Sheep in our case. Could be pigs. Depends on the size.

16 Q. And why sheep or pigs?

17 A. They have a vessel diameter that allows you to test them,
18 so that's the main reason.

19 Q. And in the animal world, would those be the animals that
20 have a cava that's closest to the human cava?

21 A. Not in the whole animal world, but in the practical animal
22 world for testing these sorts of things.

23 Q. Thanks for that clarification.

24 In the easily accessible animal world. Is that right?

25 A. Fair enough. Yes.

1 MR. ROGERS: Can we pull up Exhibit 5301, please?

2 And, Your Honor, I move this into evidence.

3 MR. O'CONNOR: No objection.

4 THE COURT: Admitted.

5 (Exhibit No. 5301 admitted into evidence.)

6 MR. ROGERS: May we publish?

7 THE COURT: You may.

8 BY MR. ROGERS:

9 Q. And, Mr. Carr, can you tell us what this document is that's
10 on the screen right now?

11 A. It's the report for the animal study for the G2 filter.

12 It's called the G1A here, but it is the same filter.

13 Q. All right. And was that -- tell us about G1A. Was that a
14 different name for the same filter?

15 A. Yes, it just was a transition.

16 Q. And let's go to page 9, please.

17 And up there in Table 3, under the analysis of data,
18 what is this test result? What does it show?

19 A. It shows an assessment for the various characteristics on
20 the left column for the filters that were tested.

21 MR. ROGERS: All right. And, Scott, if you would take
22 that down, and then go to the conclusions and pull that out,
23 please.

24 BY MR. ROGERS:

25 Q. All right. And, Mr. Carr, tell us about the conclusions.

1 What were they?

2 A. The conclusion was that the G1A design, the G2 in this
3 case, can feasibly meet customer need and performance
4 requirements that this study was designed to assess.

5 MR. ROGERS: All right. Scott, you can take that
6 down, please. And can you pull up Exhibit 5304.

7 And, Your Honor, I move this into evidence.

8 MR. O'CONNOR: No objection.

9 THE COURT: Admitted.

10 (Exhibit No. 5304 admitted into evidence.)

11 MR. ROGERS: May we publish?

12 THE COURT: You may.

13 BY MR. ROGERS:

14 Q. All right, Mr. Carr. Can you tell the jury what we see
15 here.

16 A. This is a report for a second animal study for one that's
17 chronic. So it continues.

18 Q. And so explain the difference between these two animal
19 studies. You used the word "chronic." What do you mean by
20 that?

21 A. So it's what I mentioned before: In one set we implanted
22 the filters and then left them in to study them; and then in a
23 second set, we implanted them, removed them, and then assessed
24 them.

25 Q. All right. And would you go to page 11, please.

1 And in this discussion of results, Mr. Carr, does it
2 indicate that there were physicians that were also helping in
3 this testing?

4 A. Yes.

5 Q. And who were those physicians, please?

6 A. Dr. Kaufman and Dr. Venbrux.

7 Q. And they're both interventional radiologists?

8 A. They are.

9 Q. All right. And, Mr. Carr, did this animal testing test for
10 filter perforation?

11 A. Yes.

12 Q. And how did it test for filter perforation?

13 A. So when we implanted the filters, as I said, one of the
14 ways we tested was we left them in place. When we sacrificed
15 the animals, we were able to open up their chest and abdomen
16 and directly visualize the filter in the vena cava, and so we
17 photographed them and assessed them that way.

18 Q. And --

19 THE COURT: One more question.

20 BY MR. ROGERS:

21 Q. Okay. And did this test also assess for filter tilt?

22 A. Yes.

23 Q. And how did it do that?

24 A. So on x-ray, you assess the orientation of the filter in
25 the vessel.

1 Q. And what were the conclusions about perforation and tilt?

2 THE COURT: That's the last question.

3 MR. ROGERS: Absolutely.

4 THE WITNESS: That it met the requirements.

5 MR. ROGERS: All right. Thank you, Mr. Carr.

6 THE COURT: All right. Ladies and gentlemen, we will
7 break.

8 MR. LOPEZ: Your Honor, we can do this on Monday, but
9 there's three exhibits from Dr. Kuo's deposition that we agreed
10 that we can offer to be admitted.

11 THE COURT: Why are we doing this with the jury still
12 here?

13 MR. LOPEZ: Pardon me?

14 THE COURT: Why are we doing this with the jury still
15 here?

16 MR. LOPEZ: Well, because it's evidence that I want to
17 have admitted. There's just three.

18 THE COURT: Let's deal with it Monday morning, because
19 we need to discuss it. So let's let them go.

20 Remember, no research, no discussion. We'll see you
21 Monday morning at 9:00 o'clock.

22 (Jury not present.)

23 THE COURT: All right. Counsel, as of the end of
24 today, plaintiffs have used 29 hours and 49 minutes; defendants
25 have used 16 hours and 32 minutes.

1 I will give you my ruling on the Rule 50 motion, I
2 expect by Monday morning, depending on how much time I have to
3 spend on it this weekend given other matters.

4 And we will plan to see you on Monday morning. Do we
5 need to deal with those exhibits now?

6 MR. LOPEZ: No, Your Honor. I apologize. I thought
7 you had to actually offer to admit in front of the jury.
8 That's the only reason why I did that.

9 THE COURT: Yeah, you do, but I think you can just
10 move them in Monday morning or at some point when you choose
11 to.

12 MR. LOPEZ: Yeah, that's fine. We can do it Monday.

13 THE COURT: Okay. Have a nice weekend.

14 MR. ROGERS: Thank you, Your Honor.

15 (Proceedings concluded at 4:32 p.m.)
16
17
18
19
20
21
22
23
24
25

C E R T I F I C A T E

I, JENNIFER A. PANCRAZ, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 29th day of September, 2018.

s/Jennifer A. Pancratz
Jennifer A. Pancratz, RMR, CRR, FCRR, CRC